TEMPORARY SUSPENSION OF DUTY ON RANITIDINE HYDROCHLORIDE

HEARING

BEFORE THE

SUBCOMMITTEE ON TRADE

OF THE

COMMITTEE ON WAYS AND MEANS
HOUSE OF REPRESENTATIVES

ONE HUNDRED FIRST CONGRESS

SECOND SESSION

ON

H.R. 3130

TO SUSPEND TEMPORARILY THE DUTY ON RANITIDINE HYDROCHLORIDE

SEPTEMBER 24, 1990

Serial 101-119

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TEMPORARY SUSPENSION OF DUTY ON RANITIDINE HYDROCHLORIDE

MONDAY, SEPTEMBER 24, 1990

HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON TRADE,
Washington, D.C.

The subcommittee met, pursuant to notice, at 4:11 p.m., in room 1100 Longworth House Office Building, Hon. Sam M. Gibbons (chairman of the subcommittee) presiding.

[The press release announcing the hearing and a copy of the bill, H.R. 3130, follow:]

FOR IMMEDIATE RELEASE
TUESDAY, SEPTEMBER 18, 1990

SUBCOMMITTEE ON TRADE #34
COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES
1102 LONGWORTH HOUSE OFFICE BLDG.
WASHINGTON, D.C. 20515
TELEPHONE: (202) 225-1721

THE HONORABLE SAM M. GIBBONS (D., FLA.), CHAIRMAN, SUBCOMMITTEE ON TRADE, COMMITTEE ON WAYS AND MEANS, U.S. HOUSE OF REPRESENTATIVES, ANNOUNCES A HEARING ON H.R. 3130, TO SUSPEND TEMPORARILY THE DUTY ON RANITIDINE HYDROCHLORIDE

The Honorable Sam M. Gibbons (D., Fla.), Chairman of the Subcommittee on Trade, Committee on Ways and Means, U.S. House of Representatives, today announced that the Subcommittee on Trade will hold a public hearing on H.R. 3130, introduced by Congressmen Tim Valentine (D., N.C.) and David Price (D., N.C.), which would suspend temporarily the duty on ranitidine hydrochloride. The hearing will be held on Monday, September 24, 1990, in the main Committee hearing room, 1100 Longworth House Office Building, beginning at 4:00 p.m.

This hearing is being conducted pursuant to the conference agreement on H.R. 1594, the Customs and Trade Act of 1990, in which an identical Senate provision (S. 1342) was not adopted. The House conferees were unable to accept the Senate provision because of strong opposition from domestic interests and the Administration. In light of the highly technical nature of the ulcer drug market, the House agreed to conduct this hearing to enable a more thorough evaluation of the competing allegations that have been made with respect to this product.

DETAILS FOR SUBMISSION OF REQUESTS TO BE HEARD:

Requests to be heard must be made by telephone to Harriett Lawler or Diane Kirkland [telephone (202) 225-1721] by close of business Thursday, September 20, 1990. The telephone request should be followed by a formal written request to Robert J. Leonard, Chief Counsel, Committee on Ways and Means, U.S. House of Representatives, room 1102 Longworth House Office Building, Washington, D.C. 20515. The Subcommittee staff will notify by telephone those scheduled to appear as soon as possible after the filing deadline. Any questions concerning a scheduled appearance should be directed to the Subcommittee office [(202) 225-3943].

In view of the limited time available to hear witnesses, the Subcommittee may not be able to accommodate all requests to be heard. Those persons and organizations not scheduled for an oral appearance are encouraged to submit written statements for the record of the hearing. All persons requesting to be heard, whether they are scheduled for oral testimony or not, will be notified as soon as possible after the filing deadline.

(MORE)

Witnesses scheduled to present oral testimony are requested to briefly summarize their written statements. The full statement will be included in the printed record.

In order to assure the most productive use of the limited amount of time available to question hearing witnesses, witnesses scheduled to appear before the Subcommittee are required to submit 150 copies of their prepared statements to the Subcommittee on Trade office, room 1136 Longworth House Office Building, at least 24 hours in advance of their scheduled appearance. Failure to do so may result in the witness being denied the opportunity to testify in person.

WRITTEN STATEMENTS IN LIEU OF PERSONAL APPEARANCE:

Any interested person or organization may file written comments for inclusion in the printed record of the hearing. Persons submitting written comments for the printed record should submit at least six (6) copies of their comments by the close of business Friday, September 28, 1990, to Robert J. Leonard, Chief Counsel, Committee on Ways and Means, U.S. House of Representatives, room 1102 Longworth House Office Building, Washington, D.C. 20515. If those filing a written statement for the record of the printed hearing wish to have their statements distributed to the press and the interested public at the hearing, they may provide 75 additional copies for this purpose to the Subcommittee office, room 1136 Longworth House Office Building, prior to the start of the public hearing.

FORMATTING REQUIREMENTS:

Each statement presented for printing to the Committee by a witness, any written statement or exhibit submitted for the printed record or any written comments in response to a request for written comments must conform to the guidelines listed below. Any statement or exhibit not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

1. All statements and any accompanying exhibits for printing must be typed in single space on legal-size paper and may not exceed a total of 10 pages.

2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.

3. Statements must contain the name and capacity in which the witness will appear or, for written comments, the name and capacity of the person submitting the statement, as well as any clients or persons, or any organization for whom the witness appears or for whom the statement is submitted.

4. A supplemental sheet must accompany each statement listing the name, full address, a telephone number where the witness or the designated representative may be reached and a topical outline or summary of the comments and recommendations in the full statement. This supplemental sheet will not be included in the printed record.

The above restrictions and limitations apply only to material being submitted for printing. Statements and exhibits or supplementary material submitted solely for distribution to the Members, the press and the public during the course of a public hearing may be submitted in other forms.

* * * * * * * * * * *

I

101ST CONGRESS
1ST SESSION

H. R. 3130

To suspend temporarily the duty on ranitidine hydrochloride.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 3, 1989

Mr. VALENTINE (for himself and Mr. PRICE) introduced the following bill; which was read twice and referred to the Committee on Ways and Means

---

A BILL

To suspend temporarily the duty on ranitidine hydrochloride.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. RANITIDINE HYDROCHLORIDE.

Subchapter II of chapter 9902. . of the Harmonized Tariff Schedule of the United States is amended by inserting in numerical sequence the following new subheading:

"		N[2-[[[5-[(dimethylamino)methyl]-2-furanyl]methyl]thio]-ethyl]-N'-methyl-methyl-2-nitro-1,1-ethenediamine, hydrochloride (RANITIDINE HYDROCHLORIDE) (Provided for in subheading 2932.19.50007).....	Free	No change	No change	On or before the close of the 3-year period beginning on the date of the enactment of this subheading	"

SEC. 2. EFFECTIVE DATE.

The amendment made by this Act shall apply with respect to articles entered, or withdrawn from warehouse for consumption, on or after the date of enactment of this Act.

The amendment made by this Act shall also apply with respect to articles entered subsequent to December 31, 1989, and upon which liquidation of the entry by the United States Customs Service has not occurred.

[By subsequent unanimous consent, the opening statement of Representative Schulze was placed in the record at this point:]

OPENING STATEMENT OF HON. DICK SCHULZE

Thank you, Mr. Chairman. I welcome the administration as well as representatives from Glaxo and SmithKline Beecham to today's hearing. As you know, this rather extraordinary session is the result of an agreement by the conferees for the recently-enacted "mini trade bill" to hold public hearings on the issue of domestic competition in the ulcer drug market.

Duty suspensions normally are considered all at one time during the course of hearings before the Committee on Ways and Means, and the Senate Finance Committee. These committees' established procedure is that if a particular duty suspension is opposed by a domestic manufacturer of a competing product and the administration also opposes it, the duty suspension will not be granted.

This was precisely the case for ranitidine hydrochloride. The administration and SmithKline Beecham oppose a duty suspension for the chemical. On that basis, this subcommittee and the Senate Finance Committee did not approve Glaxo's request. It is highly unusual after passage of the "mini trade bill" to be reviewing an individual duty suspension which has already been considered and opposed during the course of our routine hearings.

In fact, one of my own duty suspension bills was met with administration and U.S. industry opposition. Out of respect for Chairmen Rostenkowski's and Gibbons' desire to approve only noncontroversial duty suspension measures, I promptly withdrew my measure from consideration.

I note with approval Mr. Wendt's statement to the effect that these hearings are unwarranted given the current critical legislative agenda. SmithKline Beecham, a domestic manufacturer of an ulcer drug which competes with Glaxo's product, has not modified its strong opposition to the duty suspension on ranitidine hydrochloride. Likewise, the administration still does not support it.

The proposed duty suspension remains controversial and the extensive evidence of competition has not been repudiated. As a result, I continue to oppose the duty suspension for ranitidine hydrochloride and I question whether this hearing should even have taken place.

Chairman GIBBONS. The subcommittee will come to order.

This afternoon we're going to hold a hearing on H.R. 3130. The first witness is from the Commerce Department, Barbara Steinbock.

Ms. Steinbock.

STATEMENT OF BARBARA O. STEINBOCK, DEPUTY TO THE DIRECTOR, OFFICE OF INDUSTRIAL TRADE, INTERNATIONAL TRADE ADMINISTRATION, U.S. DEPARTMENT OF COMMERCE

Ms. STEINBOCK. Thank you, Mr. Chairman.

I don't have a prepared testimony for today. I do have a few comments I would like to make. Last week, when Department officials were reviewing what we would be saying at today's hearing, it became obvious to us that we needed to take the information Congress has requested into account in reviewing our position.

In the conference report on the Customs and Trade Act of 1990, the Congress made it clear that it wishes to go beyond the traditional view of miscellaneous tariff bills and look more extensively at the economic impact of suspending the duty on ranitidine hydrochloride.

Specifically, in the conference report, the Congress called for the hearing being held today and asked for a U.S. International Trade Commission (ITC) study of the domestic competition in the ulcer drug market to determine the potential impact of this provision.

In the past the Department has taken the position that lowering a duty generally is sufficient to cause an adverse impact. Given this rationale then, the objection of a competing domestic manufacturer was sufficient for the administration to object to a duty-suspension bill.

Specifically, our past position of objecting to this suspension bill because of the presence of competition does not appear now to be sufficient. In addition, we need to measure the extent of the impact. In order to do that, we would like to have the benefit of the further information that Congress, itself, is seeking in order to review the extent of the impact of the suspension. Specifically we would like the opportunity to review the information submitted at today's hearings, the ITC study referred to in the conference report, and any additional possibly business confidential information that SmithKline Beecham or Glaxo would care to submit.

We feel that in all fairness to both companies we should suspend any further views of the Department until after these hearings have allowed both companies to present further information on the economic impact. We also expect to benefit from the ITC study called for in the conference agreement. This study will give the ITC's views on the potential impact of the duty suspension.

Thank you.

Chairman GIBBONS. Thank you.

Mr. Schulze.

Mr. SCHULZE. I am somewhat taken aback by your testimony because I——

Ms. STEINBOCK. I'm sorry, sir, I can't hear you.

Mr. SCHULZE. Are you stating or inferring that the Department of Commerce doesn't understand why we are here?

Ms. STEINBOCK. I do not think I'm inferring as to why you are here. We would like the benefit of the additional information.

Mr. SCHULZE. I thought you said we needed additional information and that you were going to await the result of these hearings. That, to me, sort of infers that you don't understand that we're here because the tariff bill was held hostage and the only way that it could be released was to agree to a hearing. Are you aware of that?

And if you are not——

Ms. STEINBOCK. I have been going by what was in the conference report which said——

Mr. SCHULZE. I beg your pardon?

Ms. STEINBOCK. I've been going by what was in the conference report.

Mr. SCHULZE. No, no, no. I'm asking about whether you're aware of why we are here? In other words, that there was an agreement to hold a hearing.

Ms. STEINBOCK. I understand.

Mr. SCHULZE. Is this the usual procedure? Have you ever seen—how long have you been at the Commerce Department?

Ms. STEINBOCK. I have been at the miscellaneous tariff bill hearings for about 10 years now.

Mr. SCHULZE. Have you ever seen a proceeding like this before?

Ms. STEINBOCK. No, I have not.

Mr. SCHULZE. And so it is highly unusual. Now, are you telling me you don't understand why we're here or do you want me to explain that to you? Or do you understand why we're here?

Ms. STEINBOCK. I thought I understood, but from what you are saying, apparently my understanding may not be the same as yours.

Mr. SCHULZE. You are saying that you were not aware that the only way that the chairman of the Ways and Means Committee could get the bill through conference was to agree to hold this hearing?

Ms. STEINBOCK. I understood that he was holding the hearing to fulfill a promise in the conference agreement, but I also felt it was to gather more information about the economic impact.

Mr. SCHULZE. Did you really, in your heart, believe that?

Ms. STEINBOCK. Yes, sir, I do.

Mr. SCHULZE. Well, I think we have the authorization to take testimony under oath, but we don't. I guess, maybe it's a good thing.

Did your Department submit executive comment regarding H.R. 3130 to this committee, and if so, when?

Ms. STEINBOCK. I can't tell you the exact date. Actually I can if you will give me a second. We did submit a comment and——

Mr. SCHULZE. Well, could that have been in the form of a letter of May 1, 1990, and February 23, 1990 to Chairman Bentsen?

Ms. STEINBOCK. I have a February 23 letter to Senator Bentsen.

Mr. SCHULZE. OK. Now, was there another letter May 1 to Chairman Rostenkowski?

Ms. STEINBOCK. I'm sorry, I couldn't swear to it, but it is probable.

Mr. SCHULZE. Well, you know, we're happy for what happens in the Senate, but this is the House side.

Ms. STEINBOCK. I understand.

Mr. SCHULZE. Chairman Rostenkowski has a say in these things. May I just quote one line from this and it says, "We oppose enactment."

Have you changed your opinion?

Ms. STEINBOCK. At that time we opposed enactment based on our traditional criteria of——

Mr. SCHULZE. I'm sorry, I can't hear you.

Ms. STEINBOCK. Sorry. At that time we opposed enactment based on the original criteria.

Mr. SCHULZE. I guess what I'm asking is have you changed your opinion?

Ms. STEINBOCK. We have not changed it. We're reviewing that opinion in light of the congressional conference report request to look at the impact.

Mr. SCHULZE. OK. I have other questions, but I'm not going to waste a lot of time of the committee asking further questions. Mr. Chairman, I will ask that my opening statement be put in the record, if you will?

Chairman GIBBONS. Yes, sir, without objection, it will be put in at the beginning of the hearing.

Our colleague, Mr. Valentine, is here, and David Price, I don't see him. Is he here?

Yes, excuse me, I've got on my reading glasses, not my seeing glasses, so come on up.

STATEMENT OF HON. TIM VALENTINE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NORTH CAROLINA

Mr. VALENTINE. Thank you, Mr. Chairman and members of this subcommittee, I appreciate this opportunity and am delighted to be here this afternoon to introduce to this subcommittee, Dr. Charles A. Sanders, the chief executive officer of Glaxo Inc.

Glaxo, as you know, is among the leading pharmaceutical development and manufacturing companies in the world. I might say, Mr. Chairman, that our colleague, Mr. Price, who represents a portion of the Research Triangle Park, will also join us here. He was detained on the floor of the House.

Glaxo's U.S. corporate headquarters and research facilities are located in Research Triangle Park, N.C., which, at least the part of it where his headquarters resides, is in our district.

In addition to its prominent position in its industry, Glaxo is an outstanding corporate citizen. Few companies can match its record of contributions and service to the community in the Research Triangle area. Its chief executive officer has achieved an equally impressive record.

Dr. Sanders is an eminent physician and a distinguished leader in the field of medical research. He was formerly vice chairman of the Squibb Corp. and also served as chief executive officer of the Science and Technology Group, chairman of the Science and Technology Committee, and vice president of the corporation during his career at Squibb.

Before joining that corporation, Dr. Sanders was general director of Massachusetts General Hospital in Boston, and professor of medicine at Harvard Medical School. He has served and continues to serve as the director of a number of major corporations, charities and professional organizations.

I appreciate your inviting Dr. Sanders here today to testify on the proposed tariff suspension of ranitidine hydrochloride. Last year, I introduced a bill to suspend the duty on this imported chemical temporarily, but, unfortunately this legislation was not offered in time to be included in the tariff bill that was passed by the House.

This temporary duty suspension was, however, included as an amendment to the Senate tariff bill by a 68 to 30 vote in the full Senate. Glaxo holds a patent on ranitidine hydrochloride and therefore this chemical cannot be manufactured in the United States by any other company. By law there can be no direct domestic competitors of this product.

I believe strongly that Glaxo has a compelling case for the duty suspension. Ranitidine hydrochloride is used in the manufacture of an antiulcer drug produced by Glaxo. Three of the other four companies that manufacture antiulcer products have actively supported the proposed duty suspension.

I do not believe that this suspension would harm any domestic producer or affect the market place negatively. Dr. Sanders can explain the details of this matter far better than I, and I am grateful

for the opportunity to introduce him to the committee. Our colleague, Representative Price, has come in, Mr. Chairman, and with the subcommittee's permission I would like to yield to him for further comments.

If I may, I would need to leave in a few minutes because I have some business on the floor in which I am involved in.

Thank you, very much, Mr. Chairman.

Chairman GIBBONS. We appreciate your doing that, Mr. Valentine.

Mr. Price.

STATEMENT OF HON. DAVID E. PRICE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NORTH CAROLINA

Mr. PRICE. Thank you, Mr. Chairman.

I want to express my gratitude for your convening this hearing today. Suspending the duty on ranitidine hydrochloride will have important benefits for employment in my district and it makes perfect sense as public policy. After hearing the testimony today, I hope that you will agree.

I'm pleased that you have invited Charles Sanders to testify on this important issue. Dr. Sanders has a distinguished record of service in the medical profession in both the academic and corporate world. I also appreciate the support he and Glaxo have given to projects in North Carolina. They are excellent corporate citizens. I know he is well versed in this particular issue, so I believe it will be informative for the members of this subcommittee to hear from him.

I thank you again for scheduling this important hearing.

Chairman GIBBONS. Thank you, sir.

Go right ahead, Dr. Sanders.

STATEMENT OF CHARLES A. SANDERS, M.D., CHIEF EXECUTIVE OFFICER, GLAXO INC., RESEARCH TRIANGLE PARK, N.C.

Dr. SANDERS. Thank you, Mr. Chairman and members of the panel. Thank you Congressman Price and Congressman Valentine for that very generous introduction.

We believe that the duty on ranitidine hydrochloride should be suspended temporarily because it is unnecessary and it is contrary to the free trade policies which have been endorsed repeatedly by the Congress and the administration.

Indeed, one of the most important issues facing our country is the promotion of free trade and promotion of foreign investment in the United States.

Now, the only legitimate purpose of a tariff is to protect the domestic manufacturer. In the case of ranitidine hydrochloride SmithKline Beecham has not demonstrated how suspension of this duty would harm their business interests.

There is no doubt that we are in competition in the market place, but it is not unfair competition and that is the major issue because that is the stuff upon which tariffs turn.

It is hard to conceive how the suspension of a duty which the Congressional Budget Office has estimated is $7 to $9 million annually could have any effect whatsoever upon a $2 billion ulcer

market annually. I might say that attached to my testimony is a study that has been commissioned by Glaxo by Edward Tower, professor of economics at Duke University, which elaborates this point and supports it.

If I might direct your attention to the chart on the left, I think it's important to point out the similarities and the differences between Glaxo and the SmithKline Beecham Corp. Both have their world headquarters in London, England. Their U.S. subsidiaries are located, in the case of Glaxo, in Research Triangle Park, N.C.; and in the case of SmithKline Beecham in Philadelphia.

The ulcer products are Zantac, and Tagamet, respectively. I should point out that Tagamet has been on the market for some 11 years and Zantac has been sold in the United States for the past 7 years. Since Zantac was introduced, it has been priced at a premium of some 25 to 30 percent over Tagamet, because we believe—and we believe the evidence in the market place has shown this, scientifically and by the acceptance of the medical profession—that Zantac is a superior product, both in terms of efficacy and in terms of safety. So despite the price differential, Zantac has been accepted as the premier ulcer product.

In terms of manufacturing, Glaxo manufactures in Zebulon, N.C., where it finishes bulk ranitidine which is imported from the United Kingdom and Singapore. By contrast, SmithKline does its primary manufacturing and all of its finishing in Puerto Rico, and by virtue of this, enjoys significant benefits under section 936. In their filing with the SEC in form 20-F, it is estimated that SmithKline save many tens of millions of dollars in taxes by virtue of their manufacture and the finishing of their primary product in Puerto Rico.

Now, we're not against section 936. That is not what this is about. We want to point out, however, that we are dealing with a situation where a competitor is saving many, many millions of dollars every year by virtue of having their manufacturing site located in Puerto Rico. The same competitor is protesting a $7 to $9 million duty suspension of a product that is manufactured in North Carolina, where Glaxo, incidentally is the largest Federal corporate taxpayer.

We believe that while the competition has been fierce and while the past 7 years have seen a lot of activity in the marketplace, we have followed the free enterprise system. We have competed fairly in the market place. We do not seek to have an unfair competitive advantage, and therefore we are hard pressed to understand why a small amount of money relative to the total market place—$7 to $9 millions versus the $2 billion market—is giving us an unfair advantage over a company which is benefitting very significantly from section 936.

Now, if I could turn here to the next chart, let me point out that there are five ulcer products that are currently in the market place—Tagamet, Axid, Carafate, Pepcid, and Zantac. The three American companies, Eli Lilly, Marion Merrell Dow, and Merck Sharp & Dohme, have given letters to us which have been sent to the committee which actively support the suspension of duty for ranitidine hydrochloride. I would like to place these in the record.

Please note that it is the three American companies which have supported the suspension. They do not view that this is a competitive problem as far as they are concerned. Note that Tagamet has no duty; Axid has no duty, both being manufactured in the United States or the Commonwealth of Puerto Rico. Carafate also has no duty, because it was suspended in the recent trade bill.

I should point out that SmithKline Beecham had an opportunity to object to a competitive product at that time and they chose not to. In terms of Pepcid, manufactured by Merck, Sharp & Dohme, a duty suspension bill is pending for its active ingredient, famotidine. That bill has been offered by Congressman Dwyer.

SmithKline Beecham has not objected to that bill. Therefore, the only company that they have objected to is Glaxo.

Under the circumstances we feel that we are dealing with a playing field which is not entirely level because we then would be, if this duty suspension bill were not passed, be the only company selling an ulcer product in this field which did not have its duty suspended.

Finally, it is the Congress which must decide matters of trade policy. This committee must weigh the evidence before it today, and as arcane or technical as some of these arguments may appear, hopefully you will decide that the duty suspension for ranitidine hydrochloride would constitute good trade policy.

Thank you, very much.

[The prepared statement and attachment follow:]

Statement of
Charles A. Sanders, M.D.
Chief Executive Officer, Glaxo Inc.
Before the
Subcommittee on Trade of the House Ways and Means Committee
United States House of Representatives
September 24, 1990

Mr. Chairman and Members of the Subcommittee:

My name is Charles A. Sanders, and I am Chief Executive Officer of Glaxo Inc.

I appreciate this opportunity to discuss the proposed legislation to suspend temporarily the duty on ranitidine hydrochloride.

Glaxo Inc. is a United States pharmaceutical company with corporate headquarters located in Research Triangle Park, North Carolina, and manufacturing facilities in Zebulon, North Carolina. Glaxo is the largest federal corporate taxpayer in North Carolina and employs 4,000 people in North Carolina and throughout the United States.

Glaxo concentrates exclusively on prescription medicines and markets pharmaceutical products in five therapeutic categories: gastrointestinal, antibiotic, respiratory, cardiovascular and dermatological.

I am here in support of legislation introduced in the United States Senate by Senators Terry Sanford and Jesse Helms on July 18, 1989 to suspend temporarily the duty on ranitidine hydrochloride. That legislation, S. 1342, passed overwhelmingly on the floor of the U.S. Senate as an amendment to its trade bill. Fourteen of the then-19 members of the Senate Finance Committee voted in favor of the legislation. The House companion bill, H.R. 3130, was introduced by Congressmen Tim Valentine and David Price on August 3, 1989. Because the legislation was introduced in the House after it had marked up its trade bill last year, the House did not consider the bill and it was not retained in conference. However, the trade bill conferees agreed that this bill could be added to a revenue bill provided that the House did not object to the merits of this legislation.

It has been the long-standing position of the drug industry to support the elimination of tariffs on all pharmaceutical products. In the unusual case of this legislation, however, one pharmaceutical company has raised an objection. We believe this objection is groundless and that the duty should be suspended on imports of ranitidine.

Ranitidine is currently manufactured in Singapore and the United Kingdom and is imported into the United States by Glaxo Inc. for use in the production of its pharmaceutical product Zantac®, a product widely used for the treatment of ulcer disease and gastroesophageal reflux disease. Ranitidine is not manufactured in the United States by Glaxo or any other U.S. manufacturer.

In 1984, Glaxo completed construction of state-of-the-art manufacturing facilities in Zebulon, North Carolina, and began processing imported ranitidine into the tablet form of Zantac. Prior to that time, Glaxo imported Zantac in finished form and marketed it to customers in the United States. Today, United States production involves 500 to 600 American workers.

35-970 0 - 90 - 2

Glaxo manufacturing facilities in North Carolina currently are producing at full capacity in order to meet the United States demand for the tablet form of Zantac. Unless capacity is expanded, the demand for Zantac will force Glaxo once again to import the finished product from abroad. Glaxo also will have to import new dosage forms of Zantac in finished form unless it constructs additional U.S. facilities for processing these dosage forms. The raw material will continue to be produced in a central location abroad in order to provide ranitidine economically and conveniently to Glaxo production facilities around the world from a central location.

Temporary suspension of a duty that artificially increases a United States processing cost would have a strong beneficial effect in the United States. Payment of the 3.7 percent ad valorem duty on ranitidine increases the cost of producing Zantac in the United States. Passage of legislation temporarily suspending duty on ranitidine would reduce production costs, allow resources to be used for the construction of much-needed new manufacturing capacity and permit the hiring of additional workers in the United States.

Duty suspension on ranitidine will not negatively affect U.S. competition.

Enactment of duty suspension legislation would not negatively affect the competitive relationship in the United States anti-ulcer market or change competitive conditions for U.S. producers in any way. The United States International Trade Commission Report on S.1342 defined the anti-ulcer market to include the H2-antagonists Zantac, Tagamet (marketed by SmithKline Beecham), Pepcid (marketed by Merck Sharp & Dohme), and Axid (marketed by Eli Lilly & Co.), and one non-systemic cytoprotective product, Carafate (marketed by Marion Merrell Dow).[1]

H2-antagonist anti-ulcer drugs work by inhibiting acid secretion in the stomach, providing an alternative to surgery. Tagamet was the first H2-antagonist to be marketed in the United States. Since the introduction of Tagamet, additional H2-antagonist anti-ulcer drugs have been developed and introduced. These drugs are distinct from Tagamet and for this reason have created a new generation of H2-antagonist drugs that increasingly compete with each other for a share of the U.S. anti-ulcer market.

Carafate, also an anti-ulcer drug, predates Tagamet in the United States. Carafate forms a shield over the affected portion of the stomach, allowing ulceration to heal. Although not an H2-antagonist, Carafate competes with anti-ulcer products, as demonstrated by promotional literature in the industry.

Producers of Pepcid, Axid and Carafate have raised no objection to suspension of duty on ranitidine. Only SmithKline Beecham, the manufacturer of Tagamet, has objected.

Zantac is a second generation H2-antagonist.

In 1983, Zantac was approved for marketing in the United States by the Food and Drug Administration. Zantac is a second generation H2-antagonist. Although like Tagamet, Zantac treats ulcer disease, it is distinct from Tagamet in many ways. In contrast to Tagamet, which is characterized in molecular

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[1]United States International Trade Commission, Memorandum to the Committee on Finance of the United States Senate on S. 1342, 101st Congress, A Bill to Suspend Temporarily the Duty on Ranitidine Hydrochloride, November 29, 1989 at page 3.

structure by an imidazole ring, Zantac is characterized by a non-imidazole ring structure. Tagamet tends to inhibit cytochrome metabolism, and has historically had an incidence of drug interactions with several pharmaceutical products. Zantac has consistently over time maintained a positive safety profile and presents significantly less drug interaction concern than Tagamet. Zantac has been shown to be superior to Tagamet for maintenance therapy administered to many patients at risk for recurrent ulcer disease. Moreover, Zantac is indicated for treatment of gastroesophageal reflux disease. Tagamet is not.

Because at the time of initial marketing of Zantac, Glaxo believed that its product was of superior value and represented a new generation in the anti-ulcer market, Zantac was priced approximately 25 percent above Tagamet and consistently has remained at approximately the same percentage premium. Despite the fact that Zantac is the more expensive drug, because of the confidence prescribers have shown in the product, Zantac's market share has grown and the product has achieved market penetration in the anti-ulcer market.

In 1987 and 1988, two other second generation drugs were introduced into the United States market. Both Pepcid and Axid were priced above Tagamet, within a few percentage points of the price of Zantac. Both have molecular structures that, like Zantac, are characterized by a non-imidazole ring structure.

The second generation drugs are capturing the market.

Market share trends demonstrate that Tagamet is losing sales to the newer second generation drugs, Pepcid and Axid. As is evident from the chart below, Zantac has achieved a mature market share of a still expanding market and is not taking any appreciable market share away from Tagamet. (See Exhibit A.)

Zantac, Axid and Pepcid represent the new generation H2-antagonist drugs. Market share is shifting away from the older drug, Tagamet, to this new generation. The competitive trends in the anti-ulcer market are responsible for Tagamet's loss of market share. Granting duty suspension for ranitidine will have no effect on those established trends.

The duty suspension, which amounts to $7-9 million annually, is minuscule compared with the $2 billion anti-ulcer market.

If money saved from duty suspension were used to lower the price of Zantac, no competitive harm would result to SmithKline Beecham. Suspension of duty would allow Glaxo to invest in expanded production capacity in the U. S. However, even if Glaxo were to pass the duty along to consumers in the form of a price reduction, no competitive harm would result to SmithKline Beecham or other manufacturers in the anti-ulcer market. As stated above, since its introduction into the market, treatment with Zantac has been priced at 25 percent above treatment with Tagamet. If the price of Zantac were reduced based on the amount saved on the duty, treatment with Zantac would be only pennies less per day. If price were the determining factor of sales in the anti-ulcer market, Tagamet not Zantac, would hold the leading position in the market.

No objections have been raised for suspension of duty on raw materials used in anti-ulcer products other than ranitidine.

In the interest of fairness, tariffs should be suspended for ranitidine on the same basis as that used for other raw materials not produced in the United States and used in the production of U.S. pharmaceutical products. SmithKline Beecham has raised objection to the suspension of duty on ranitidine. It has raised no objection to suspension of duty on raw materials used in other ulcer medications that compete with Tagamet.

In response to SmithKline Beecham's objection, the Department of Commerce found duty suspension for ranitidine to affect competition. The Department made no objection to suspension of duty for other products in the anti-ulcer market that compete with Tagamet. As recently reported to the Senate Finance Committee there was no objection to S. 2060, a bill to suspend duty on sucralfate, used to manufacture Carafate and because no objection was raised, this bill was included in the recent trade bill (H.R. 1594), which was signed into law on August 20, 1990 as P.L. 101-382. Although the Department of Commerce, when confronted with this inequity, attempted to distinguish Carafate from Zantac because it works differently in the stomach, Carafate is clearly recognized as a competitor in the anti-ulcer market by authorities such as the International Trade Commission, Carafate's manufacturer (Marion Merrell Dow) and by the pharmaceutical industry as a whole.

Even if Carafate could be distinguished from H2-antagonist ulcer medicines, certainly Pepcid cannot. This session, H.R. 4648 was introduced in the United States House of Representatives to request suspension of duty on famotidine, the active ingredient of Pepcid. Glaxo was contacted by a Department of Commerce representative to determine if the company would take a position on this bill. Glaxo has a policy not to oppose such bills. Subsequently, Glaxo has been informed informally by Department of Commerce representatives that the Department does not intend to oppose suspension of duty for famotidine.

SmithKline Beecham did not raise objections to duty suspension for sucralfate. Glaxo has been informed that SmithKline Beecham has raised no objection to duty suspension for famotidine, despite loss of market share of Tagamet to Pepcid during the last two years. SmithKline Beecham has only objected to duty suspension for ranitidine. The objections by SmithKline Beecham and subsequently by the Department of Commerce are both inconsistent with treatment of other products in the same therapeutic class and unfair.

SmithKline Beecham has alleged that duty suspension on ranitidine puts other producers that must pay duty at a competitive disadvantage. In the anti-ulcer market, only sucralfate for Carafate, famotidine for Pepcid and ranitidine for Zantac are subject to duty. Duty suspension is in effect for sucralfate and is anticipated for famotidine. No producer of anti-ulcer products other than Glaxo is likely to pay a duty. In fairness, ranitidine should be treated the same way.

The Department of Commerce has provided no rationale for raising objections to the temporary suspension of duty on ranitidine other than the fact that SmithKline Beecham produces an anti-ulcer medication. It is important to note that Merck and Lilly, manufacturers of Pepcid and Axid, the other second generation H2-antagonist anti-ulcer drugs, have not objected to suspension of duty on ranitidine. In addition, Marion Merrell Dow, the manufacturer of Carafate, has written to the United States International Trade Commission in support of duty suspension on ranitidine. (See Exhibit B).

Duty suspensions are routinely granted for raw materials imported for use by U.S. manufacturers even when, as in the case of ulcer medications, competing drugs exist in the same therapeutic category.

The existence of competing domestic products in the same therapeutic category has not prevented the United States Department of Commerce from making affirmative recommendations on suspension of duty for similarly situated compounds.

There are numerous examples of suspensions of duty on raw material ingredients used in pharmaceutical products even when

competing products in the same therapeutic class are manufactured in the United States. In addition to sucralfate, the recent trade bill, P.L. 101-382, included other duty suspension provisions for chemicals used in pharmaceuticals. A duty suspension was included in that legislation for cefixime, a raw material used by Lederle Laboratories in the production of the antibiotic Suprax. Suprax competes with Glaxo's Ceftin, Lilly's Ceclor and SmithKline Beecham's Augmentin. SmithKline Beecham raised no objection to that duty suspension. A duty suspension provision was included in the trade bill for amiloride hydrochloride, a raw material used by Merck in the manufacture of the diuretics Midamor and Moduretic. These products compete with Dyazide, a product manufactured by SmithKline Beecham. SmithKline Beecham raised no objection to duty suspension for amiloride hydrochloride.

Other duty suspension provisions in the recent trade bill for chemicals used in the production of products with United States therapeutic competition include the following: 1) duty suspension on teicoplanin, used by Marion Merell Dow in the production of Targocid. Targocid competes with Lilly's Vancocin; 2) duty suspension on diltiazem hydrochloride, used by Marion Merrell Dow in the manufacture of Cardizem for cardiovascular therapy. Cardizem is a calcium channel blocker that competes with Pfizer Inc.'s Procardia, G. D. Searle & Co.'s Calan and Knoll Pharmaceutical's Isoptin, among others; 3) duty suspension on ADC-6, used by Merck in the manufacture of Primaxin, an antibiotic that competes with SmithKline Beecham's Tazicef. Note that SmithKline Beecham did not object to suspension of duty on ADC-6; 4) duty suspension on ceftazadime tertiary butyl ester, used by SmithKline Beecham in the production of Tazicef for injection, a cephalosporin-type antibiotic. Other U.S. competitors in the cephalosporin antibiotic market include Lilly's Tazidime, Hoffmann-La Roche Inc.'s Rocephin, Merck's Primaxin, Hoechst-Roussel Pharmaceuticals Inc.'s Claforan and Pfizer's Cefobid; and 5) duty suspensions on ciprofloxacin hydrochloride used by Miles in Cipro and norfloxacin used by Merck in Noroxin, both of which compete with Dista Products Company's Cinobac. These are only a few examples of suspensions of duty permitted on compounds not manufactured by a U.S. producer whose final product faces therapeutic competition from U.S. manufacturers. SmithKline Beecham failed to raise objections to any of these duty suspensions. In addition, in none of the instances in which SmithKline Beecham products faced domestic competition did its competitors express opposition.

<u>Any competitive advantage to Glaxo resulting from duty suspension would be more than offset by the tax advantages enjoyed by SmithKline Beecham from Section 936 tax credits.</u>

Any potential advantage to Glaxo resulting from duty suspension is more than exceeded by advantages that SmithKline Beecham gains from the tax credits under Section 936 of the Internal Revenue Code. Section 936 excludes from U.S. taxation certain profits earned from Puerto Rican manufacturing operations. To take advantage of this tax credit, SmithKline Beecham manufactures virtually all of its cimetidine, the active ingredient used in Tagamet, and the finished Tagamet product in Puerto Rico.

According to SmithKline Beecham's own Form 20-F for the last fiscal year submitted to the Securities and Exchange Commission, SmithKline Beecham's benefit from tax-exempt income in Puerto Rico and Ireland amounted to tax savings of $88 million last year. Because all of SmithKline's Tagamet is produced in Puerto Rico, the Section 936 tax credit clearly gives SmithKline Beecham a competitive advantage over companies like Glaxo that produce their anti-ulcer drugs domestically. SmithKline Beecham's Section 936 tax credit on profits from its $527 million sales of

Tagamet is far in excess of the $7 million duty suspension on ranitidine.

SmithKline Beecham, therefore, already receives significant tax credits that give it a competitive advantage far in excess of any advantage Glaxo might gain from suspension of a duty.

Denial of duty suspension for ranitidine is in direct opposition to U.S. policy.

United States policy favors reduction of duty across the board in an effort to encourage free trade among nations. The Bush administration has taken a position to support the "double zero option" for pharmaceuticals, a reciprocal duty-free agreement to eliminate tariff barriers for pharmaceuticals.

Glaxo's request for the temporary suspension of duty for ranitidine is consistent with the stated U.S. policy. Suspension of duty on ranitidine would demonstrate the commitment of Congress and the U.S. government to this principle and encourage other nations to take similar actions to foster free trade.

The Pharmaceutical Manufacturers Association, the trade association of the pharmaceutical industry, has consistently supported the U.S. position on this issue. Glaxo and other pharmaceutical manufacturers have demonstrated their support by not opposing bills that provide for suspensions of duty for chemicals used in the production of pharmaceuticals. By opposing duty suspension for ranitidine, SmithKline Beecham and the Department of Commerce take a position in direct opposition to established U.S. trade policy.

The duty on ranitidine should be suspended temporarily.

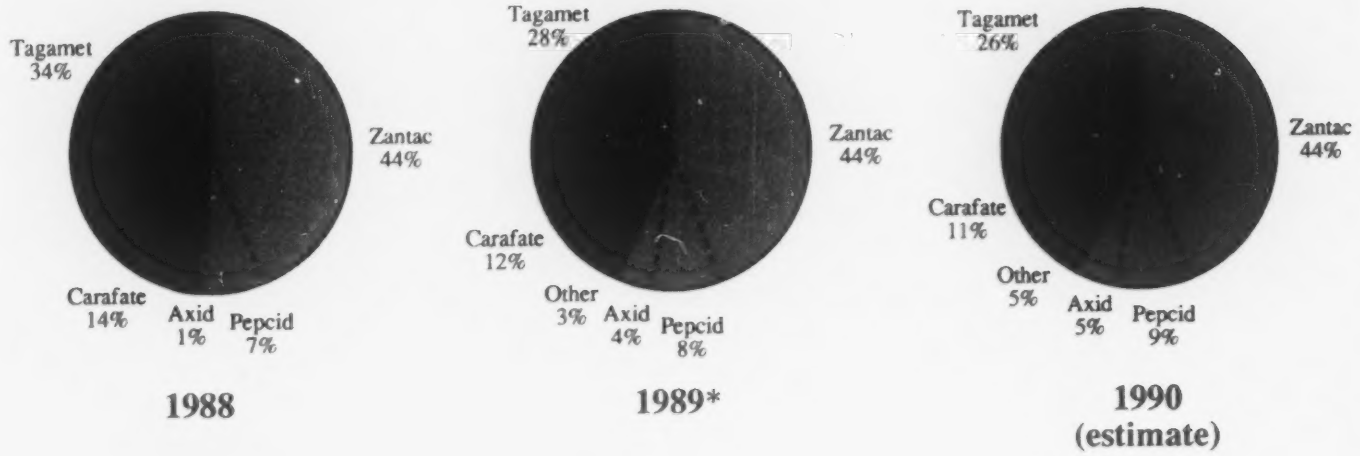
In conclusion, I respectfully request support for temporary suspension of the duty on ranitidine. Enactment of this legislation would have no effect upon the competitive relationship between Zantac and the other drugs in the U.S. anti-ulcer market. The market share held by Zantac is based primarily on the value of the medication, not on price differentials. Suspension of duty on ranitidine would not affect competition in the anti-ulcer market.

Duty suspension for ranitidine should be reviewed by the same criteria as used for other raw materials used in pharmaceutical products. Suspension of duty has been approved for other products in the anti-ulcer market that compete with Zantac. Fairness demands that Zantac receive the same concession.

SmithKline Beecham should not prevail in its opposition to temporary duty suspension on ranitidine. It has failed to demonstrate any harm to its competitive position in the U.S. market resulting from the duty suspension. Moreover, the Department of Commerce also has provided no basis for finding that SmithKline Beecham would be harmed by suspension of duty on ranitidine. If one company can defeat suspension of duty without cause, the result can only be a chaotic trade policy steered by the unfounded objections of a single company. Decisions involving trade should be made by the U.S. Congress on the merits of each case. Such decisions are too important to leave to the whim of a single company.

Ranitidine is not manufactured in the United States. The current duty on ranitidine does not protect any U.S. manufacturer. It merely increases the domestic production cost of Zantac and should be suspended.

Brand Share Trends in the Anti-Ulcer Market



1st generation H_2-antagonist

2nd generation H_2-antagonists

Other anti-ulcer products

* Percentages may not add up to 100% due to rounding

Source: IMS, New Prescription Audit

Exhibit A

EXHIBIT B

MARION LABORATORIES, INC.
P.O. BOX 8480 • KANSAS CITY, MISSOURI 64114-0480 • 816-966-4000

January 15, 1990

Ms. Elizabeth Nesbitt
International Trade Analyst
International Trade Commission
500 E Street, S. W.
Washington, D. C. 20436

Dear Ms. Nesbitt.

I am writing to request that my original correspondence regarding Marion Laboratories' position on S. 1342, dated August 16, 1989, be reconsidered.

Marion Laboratories recently merged with Merrell Dow Pharmaceuticals Inc. making the new company, Marion Merrell Dow Inc., an international pharmaceutical manufacturer. Because of this change from a domestic to an international corporation, Marion Merrell Dow Inc. takes a different position on S. 1342.

We would like to withdraw Marion Laboratories' objection to S. 1342 and its companion bill, H. R. 3130. Marion Merrell Dow Inc. supports the free-trade concept and feels that import duties for pharmaceutical products impede trade. In addition, we support the elimination of global pharmaceutical tariffs and feel passage of S. 1342 is a positive step in that direction.

You may also be interested to know that Philip Ellsworth has been named as Vice President of Government and Industry Affairs for Marion Merrell Dow International. I am pleased to know that you and Philip have worked closely together in the past, and I look forward to working with both of you in the future.

Thank you for reconsidering my comments. If you need additional information, or have questions, please do not hesitate to contact Philip or me.

Sincerely,

Jerry B. Hedrick
Vice President
Government Affairs
JBH:mgr

GLAXO		SMITHKLINE BEECHAM
LONDON, U.K.	WORLD HEADQUARTERS	LONDON, U.K.
RESEARCH TRIANGLE, NORTH CAROLINA	U.S. SUBSIDIARY HDQTRS	PHILADELPHIA, PENNSYLVANIA
ZANTAC® RANITIDINE	ULCER PRODUCT	TAGAMET® CIMETIDINE
$78.79	30-DAY SUPPLY PRICE	$62.55
ZEBULON, NORTH CAROLINA	MANUFACTURING SITE	PUERTO RICO SEC. 936 FACILITIES
NO	SEC. 936 TAX ADVANTAGE	YES

U.S. PRESCRIPTION DRUG
ANTI-ULCER MARKET

DRUG	MANUFACTURER	TARIFF TREATMENT
Tagamet® (cimetidine)	SmithKline Beecham	No duty - manufactured in Puerto Rico
Axid® (nizatidine)	Eli Lilly	No duty - manufactured in Indiana
Carafate® (sucralfate)	Marion Merrell Dow	No duty - suspended by P.L. 101-382
Pepcid® (famotidine)	Merck	Duty suspension pending - H.R. 4648 (Dwyer)
Zantac® (ranitidine)	Glaxo	Duty suspension pending - H.R. 3130 (Valentine/Price)

Statement of

Edward Tower, Ph.D.

Professor of Economics

Duke University

September 18, 1990

I have examined the economic issues surrounding the legislation requesting duty suspension on the importation of ranitidine hydrochloride. I have reached the conclusion that duty suspension would not negatively affect the competitiveness of the anti-ulcer market.

To put this issue in perspective, it is useful to first discuss the general nature of competition in a research intensive industry like pharmaceuticals. Competition in this industry centers around the introduction of new products capable of earning significant market shares on a global basis. Economic success is associated with the introduction of new products that offer a new therapeutic benefit which is effectively communicated to physicians.

It is useful to examine the anti-ulcer market from this perspective. The first H2-antagonist introduced into the market was Tagamet® by SmithKline Beecham in the late 1970s. This drug offered an important advance over established products and provided significant savings over other forms of medical treatment for ulcers such as surgery. As a

result, this product enjoyed phenomenal economic success, dominating the anti-ulcer market and eventually becoming the largest selling prescription drug in the U.S. market and the world market.

In 1983, Zantac® was launched in the U.S. This represented a second generation of H2-antagonist products. Zantac has a different molecular structure than Tagamet. Zantac has a ring structure compared to the chain formation of Tagamet. From a therapeutic standpoint, it also has fewer interactions with other medicines and has a more favorable side effect profile than Tagamet. As a result, Zantac immediately began to capture market share from Tagamet. This was the case even though Zantac was launched at a significantly higher price.

Two other H2-antagonists were subsequently launched into the anti-ulcer market, Pepcid® in 1987 and Axid® in 1988. These products resemble Zantac in molecular structure and therapeutic qualities. They also are priced at a significant premium to Tagamet (but at a slight discount compared to Zantac).

Brand market shares in the anti-ulcer market over the period 1984-90 are presented in Table 1. This table shows that by the late 1980s Zantac had supplanted Tagamet as the market leader even though it has continued to maintain a price premium over Tagamet. Table 1 also shows that Pepcid and Axid have generally taken market share away from Tagamet, the initial entrant into the market, rather than

from Zantac, the new market leader that they more closely resemble. This reflects their therapeutic advantage over Tagamet.

This observed pattern of competition in the anti-ulcer market is not atypical of the pharmaceutical marketplace. This dynamic scenario has been documented elsewhere in terms of other therapeutic product classes.[1] The main factor affecting the competitiveness of Tagamet and the other anti-ulcer medicines is the potential entry into the market of new products with therapeutic advantages relative to these existing products. In this regard, a new type of anti-ulcer medication, Losec®, was recently introduced into the U.S. market. Also, several anti-ulcer products are currently in the research and development pipeline and should be introduced into the market in the near future.

Another feature of new entry into the anti-ulcer market is shown in Table 2. In particular, new entry has resulted in declining concentration in this market. The share held by the top ranked firms has steadily declined in the face of new products being launched into the market. This is symptomatic of a vigorously competitive market as reflected in the dynamic movement in the degree of industry concentration.

In this kind of market, duty suspension for Zantac will not have an anti-competitive effect on SmithKline Beecham or any other firms operating in the marketplace. In particular, let us look at the worst case scenario for

SmithKline Beecham. For the sake of analysis, let us suppose that duty suspension is granted and Glaxo uses it to reduce the price of Zantac. The Congressional Budget office estimates the amount of duty on ranitidine to be $7 million a year. Glaxo's revenues from sales of Zantac tablets in the United States are in excess of $1.2 billion a year. Reduction in the price of Zantac by the amount of the duty would represent a price reduction of 0.58 percent. The most widely sold bottle of Zantac contains 60 tablets of Zantac 150mg. The average wholesale price is $78.79 a bottle. A price reduction of 0.58 percent is a reduction of 46 cents per bottle. The most widely prescribed dosage of Zantac is two tablets per day. Consequently, in the unlikely event that Glaxo reduces its price by the full amount of duty suspension, the price reduction would reduce the cost of using Zantac by approximately 1.5 cents per day.

As noted, Zantac has sold at a significant premium over Tagamet throughout its U.S. history (currently on the order of 25-26 percent). A price reduction of less than 6 tenths of 1 percent would still leave Zantac with a sizeable price premium compared to Tagamet. A price change of this magnitude would have a negligible effect on the market shares realized by Zantac and Tagamet. A drop in the cost of using Zantac of less than 2 cents per day is unlikely to cause any physicians or hospitals currently using Tagamet to switch to Zantac.

Import duties on drug inputs do have an important influence on the location of manufacturing facilities. Drugs typically have a high ratio of value to weight, so they have low transport costs as a proportion of price and production cost. Furthermore, the same drug is typically consumed in many countries. These two factors mean that production facilities may feasibly be located in several alternative sites. Keeping duties on inputs into existing drugs low is an important factor in locating production sites in the United States.

Glaxo currently manufactures Zantac abroad as well as in the United States. Consequently, small cost differentials may result in large production shifts between the two locations. Therefore, to assure that new production facilities for Zantac continue to be placed in the U.S., keeping the cost of U.S. production low through duty suspension is important.

Duty suspension by the U.S. on inputs into existing drugs will also affect the location of new facilities to produce new drugs. Duty suspension on current inputs signals the intention to suspend duty on inputs into future drugs and encourages the location of production sites for new drugs in the United States. Consequently, if the United States wishes to encourage the domestic production of products which embody high technology research and development, in order to reap the externalities from

research and development, it should suspend duties on pharmaceutical inputs.

Duty suspension also raises important tariff negotiation issues. In a letter of April 25, 1990, Robert Mosbacher, the Secretary of Commerce, writes about his opposition to the bill for duty suspension of ranitidine hydrochloride to Congressman Cass Ballanger. He writes "...we generally feel that tariff reductions should be made in the context of trade negotiations. Such negotiations provide opportunities to gain concessions from other countries and export opportunities for U.S. manufacturers."

Considering the duty suspension on ranitidine in the context of trade negotiations, as Secretary Mosbacher suggests, I find that suspension of this duty would be likely to strengthen rather than weaken the U.S. trade negotiating position.

Let us examine this issue specifically concerning Zantac. Zantac is produced in the United Kingdom, both in injectable and tablet form. The import tariff of 6.3 percent on the final product, Zantac, in both tablet and injectable form is currently higher than the tariff of 3.7 percent on the input, ranitidine. This constitutes an incentive for Glaxo to locate production of Zantac in the U.S. in order to reduce total duty paid. Consequently, this tariff structure makes it attractive to produce in the United States. The suspension of the duty on the input would make it even more attractive to produce the final

product in the United States. The EC can be expected to react to suspensions of this sort by reducing its own tariff barriers.

This is because, with respect to trade negotiations with the European Community (EC), suspension of duty on a raw material makes manufacturing the final product more attractive in the United States and relatively less attractive in the EC. To counter this, the EC is more likely to lower tariff barriers to encourage the manufacture in the EC by U.S. producers of other products.

Moreover, from a more general perspective, the denial of duty suspension acts as a signal concerning future government behavior toward the industry. The collection of an import duty on any drug input is effectively a tax on the sale of that drug. In the past, drug inputs have generally entered the U.S. duty free as drug companies have typically not objected to petitions by competitors for duty suspensions, so the effective input tariff was zero. If, in the future, the practice of duty suspension is generally eliminated, this would amount to a new tax on the drug industry as a whole. In the short run, where most costs are sunk, such a tax will not appreciably raise price and shrink output and variety. However, the signal sent by such a tax is a disincentive for innovation and new product competition. Over several years, innovation and new product development appreciably affect the variety of drugs available. Consequently, such taxation of the drug industry will depress jobs in research and development immediately. It will also depress consumer welfare by reducing variety and raising prices primarily in the longer run.

Table 1
Percentage Share of New Prescriptions
in the Anti-Ulcer Market

Drug	1984	1985	1986	1987	1988	1989	1990
Tagamet	69%	62%	53%	42%	34%	28%	26%
Zantac	26%	30%	37%	41%	44%	44%	44%
Carafate	5%	7%	9%	12%	14%	12%	11%
Pepcid	--	--	*	5%	7%	8%	9%
Axid	--	--	--	*	1%	4%	5%
Cytotec	--	--	--	--	*	3%	3%
Losec	--	--	--	--	--	*	2%
Total	100%	100%	100%	100%	100%	100%	100%

* Less than .5%

Note: The 1990 estimate is based on the twelve consecutive months from 7/89 - 6/90. Percentages may not add to 100% due to rounding.

Source: IMS Database, New Prescription Audit

Table 2

Degree of Concentration in the Anti-Ulcer Market

Share held by:	1984	1985	1986	1987	1988	1989	1990
Top 2 competitors	95%	92%	90%	83%	78%	72%	70%
Top 3 competitors	100%	100%	99%	95%	92%	89%	81%
Top 4 competitors	NA	NA	100%	100%	99%	92%	90%

Note: The 1990 estimate is based on the twelve consecutive months from 7/89 - 6/90.

NA - There were only 3 competitors in the market in 1984 and 1985.

Source: IMS Database, New Prescription Audit

Endnote

[1] Bond, Ronald S. and David F. Lean. Sales, Promotion and Product Differentiation in Two Prescription Drug Markets. Staff report. Washington, D.C.: Federal Trade Commission: February 1977;

Cocks, D.L. "Product Innovation and the Dynamic Elements of Competition in the Ethical Pharmaceutical Industry." In: Helms, R.B., ed. Drug Development and Marketing. Washington, D.C.: American Enterprise Institute: 1975; 225-254;

Grabowski, Henry and John Vernon. "Government Policy and Innovation in the Pharmaceutical Industry." In: Nelson, Richard R., ed. Government and Technical Progress, A Cross-Industry Analysis. New York, N.Y.: Permagon Press: 1982; 283-360; and

Scherer, F.M. and David Ross. "Product Differentiation, Market Structure and Economic Performance." 3rd ed. In: Industrial Market Structure and Economic Performance. Boston, Mass.: Houghton Mifflin Company: 1990; 571-611.

Chairman GIBBONS. Mr. Schulze.

Mr. SCHULZE. Just very briefly. Did you say where ranitidine hydrochloride is produced? Did you say Singapore?

Dr. SANDERS. It is produced in the United Kingdom and Singapore.

Mr. SCHULZE. In the United Kingdom and Singapore?

Dr. SANDERS. Yes, sir.

Mr. SCHULZE. Can you tell someone who is not a chemist how it is produced; what it's made out of or is that top secret?

Dr. SANDERS. No, it is not top secret. I'm not a chemist either, Congressman. It is kind of hard for me to say.

Mr. SCHULZE. I guess what I'm wondering is why it cannot be produced in the United States and maybe you can tell me?

Dr. SANDERS. Well, it certainly could be produced in the United States. No U.S. producer—no one produces it in the United States at the moment. We are a worldwide company and we have a global strategy.

Mr. SCHULZE. So you just buy it, you don't produce it?

Dr. SANDERS. We produce it, sir. We produce it in the United Kingdom and we produce it in Singapore.

Mr. SCHULZE. But it could be produced in the United States?

Dr. SANDERS. Yes, sir.

Mr. SCHULZE. Are there reasons why it is not produced in the United States, and why it is produced in Singapore and the United Kingdom?

Dr. SANDERS. It is produced in the United Kingdom and Singapore because it is a matter of distribution and global strategy that makes the compound readily available to the markets which need it. That was a strategy which was decided on many, many years ago and to relocate that primary production to the United States is not strategically wise and would be very costly. It is not something which is going to be done.

We will continue to finish ranitidine in those markets where we sell it, and that is what is done here. We finish it in the United States and sell it in the United States.

Mr. SCHULZE. Well, I presume a greater share of the market would be in the Pacific Rim and in Great Britain. A greater share of the market—you say that it would be inefficient to produce in the United States, so I presume the greatest market share—if I were manufacturing something I would do it as close to the source of greatest sales as possible—so I am perhaps incorrectly assuming that you said it would be inefficient to move it. That is where the big sales are. Is that true?

Dr. SANDERS. Not entirely true. The largest market, of course, is the United States but our major manufacturing facilities of ranitidine historically have been in the United Kingdom and in Singapore. To add a third facility would not be prudent as far as the economics of the primary manufacture.

Mr. SCHULZE. OK, I guess I am somewhat confused but I don't want to confuse the issue further. But you say it's not a matter of cheaper labor or a closer supply or any of those things; it is just a matter of some kind of strategy?

Dr. SANDERS. It's a matter of economics in terms of worldwide strategy for manufacture and distribution of primary chemical substances. Ranitidine is not the only substance that is manufactured at these sites and there is an economy of scale which is associated with having all your chemical facilities in no more than one or two sites.

Mr. SCHULZE. You say that these substances are different. That Zantac and Tagamet do not compete for the ultimate user or the same market?

Dr. SANDERS. Oh, yes, very much so. They are different chemically.

Mr. SCHULZE. They are different chemically.

Dr. SANDERS. And it is for that reason that we have been able to show through time that Zantac is a safer compound in terms of side effects and interaction with other drugs.

Mr. SCHULZE. Stop me if I am wrong, but I understand that the FTC wrote to you and said to you that you are not allowed to use that statement. It was not a cease and desist but I understand that they—if I'm incorrect, please correct me—that the FTC wrote and said that you are not allowed to use that statement in advertising and in statements to doctors and so forth, is that correct?

Dr. SANDERS. No, sir, that is not correct.

Mr. SCHULZE. The FTC did not write to you?

Dr. SANDERS. The FDA, Congressman.

Mr. SCHULZE. The FDA, I'm sorry.

Dr. SANDERS. The FDA wrote us a letter on May 19, 1986, and it was the culmination of a number of letters which had been exchanged between Glaxo and the FDA which related to statements that we had made to the Medicaid advisory committees of the States of California and Hawaii. They took exception to those statements. These were statements which were never used in promotion. They were never exposed to physicians. We pointed out to the FDA that we did not think they had jurisdiction in this negotiation. We exchanged letters and nothing further was heard.

I might add that the promotion of various medications is monitored very stringently by the FDA.

Mr. SCHULZE. I have just been handed a copy of a letter dated May 19 and I quote, if it is correct, "We consider the letter to be labeling for Zantac and the information contained therein to be misleading, false and otherwise violative of the Federal Food, Drug and Cosmetic Act."

Now, that sounds pretty clear to me.

Dr. SANDERS. I might add that on June 26, 1986, we submitted a detailed response to the FDA taking strong exception to their position and claimed, we felt that what we had said was accurate and truthful and we noted that the letter constituted a formal submission in an administrative proceeding, as I said earlier, and as such, was not promotional to physicians of the type subject to FDA regulation.

No further action was taken by the FDA.

Mr. SCHULZE. All right, so you are saying that the FDA does not believe that your claims are misleading, false or otherwise violative of the Federal Food, Drug and Cosmetic Act?

Dr. SANDERS. I don't know what the FDA believed. There was no further response forthcoming after we responded to the letter of May 19 in our letter of June 26.

Mr. SCHULZE. I'm just unclear and I guess I'm still unclear.

Dr. SANDERS. Well, I might point out that these letters are obviously of considerable concern to all of us in the industry. Indeed, I should point out that in June of 1988, my colleague who is about to testify, Mr. Wendt, received a letter from Peter Rheinstein of the FDA, which suggested false and misleading advertising on the part of SmithKline about Tagamet.

Suffice it to say that the result of this letter required SmithKline to issue a "Dear Doctor" letter, a "Dear Doctor" letter which went to every physician in the United States to correct what had been false and misleading in terms of their promotional materials sent to members of the American College of Gastroenterology. I would like to submit that as part of the record as well.

Mr. SCHULZE. Was their claim that it was safer than some other product?

Dr. SANDERS. What they were claiming was that it was being used for indications which were unapproved by the FDA. The FDA took strong exception to that and as a result, SmithKline had to issue a "Dear Doctor" letter rescinding that claim.

Mr. SCHULZE. Thank you.

Dr. SANDERS. I might add also that to my knowledge, Glaxo has never had to issue a Dear Doctor letter to all the physicians in the United States rescinding any promotional claims.

Mr. SCHULZE. I guess I'm still somewhat confused. You made the statement in your testimony that it is a safer product, did you not?

Dr. SANDERS. Yes, sir. It's our belief that it is.

Mr. SCHULZE. And you still stand behind that?

Dr. SANDERS. Yes, sir. It certainly has a wider indication for use. For example, Zantac is indicated for the treatment of gastroesophageal reflux disease, which is a very common problem in the United States. I don't know how many people have it but it is maybe

around 20 percent of the population. That is a claim that Tagamet does not have.

Mr. SCHULZE. Thank you.

Thank you, Mr. Chairman.

Chairman GIBBONS. Thank you.

Mr. Pease.

Mr. PEASE. Thank you, Mr. Chairman.

Dr. Sanders, I would like to state for the record that I'm not from North Carolina, I'm not from Pennsylvania, I'm just a simple seeker after the truth. [Laughter.]

Mr. PEASE. Can you tell me, sir, what the term of your patent is on ranitidine?

Dr. SANDERS. Yes, sir, it goes until 1995.

Mr. PEASE. 1995, and after that year, other companies would be free to manufacture that product, is that right?

Dr. SANDERS. Yes, sir.

Mr. PEASE. You are seeking a suspension of the tariff which would save you about $7 to $9 million, is that correct?

Dr. SANDERS. For 3 years, yes, sir, $7 to $9 million a year for 3 years.

Mr. PEASE. If you are successful what would happen to that $7 to $9 million?

Dr. SANDERS. Well, sir, as Congressman Valentine and Congressman Price indicated, we have made very substantial investments in North Carolina. A good example of that is that on October 18, we will be dedicating a $350 million R&D facility in North Carolina, which, as I understand it, is the largest commitment that has ever been made to the State of North Carolina in terms of an industry.

What we would do with the money, of course, is that we would seek to expand our manufacturing facilities in general, not necessarily related to Zantac. We employ 600 people at Zebulon in terms of manufacturing and finishing. We would expand that, and would, therefore, increase employment. We estimate that expansion would create between 80 and 150 jobs perhaps.

That is certainly one of the potential uses of that additional money.

Mr. PEASE. You did not mention reducing the cost of your product, which I note is higher than that of the product of your opponent. Have you given any thought to reducing the cost of your product to the consumers?

Dr. SANDERS. Well, we have. Actually, as it turns out, if we took the $7 to $9 million annually and used it to reduce the price of Zantac, it would reduce the cost by 1.5 cents a day, or 46 cents a month. So, in the great scheme of things that is not a lot of money and I would really prefer to use that money to invest in the State of North Carolina.

Mr. PEASE. I'm sure that the representatives of North Carolina would appreciate that too. I was trying to speak on behalf of all the Zantac purchasers in Ohio, which is my State.

Thank you, very much, Dr. Sanders.

Dr. SANDERS. Thank you, sir.

Chairman GIBBONS. Mr. Crane.

Mr. CRANE. Thank you, Mr. Chairman.

I noticed in an article in Financial Times, back in April Dr. Sanders, that your parent corporation is contemplating putting $50 million into constructing a plant in the Soviet Union for the manufacture of Zantac.

How much, if you were to get this duty suspension, how much money would you contemplate putting into North Carolina?

Dr. SANDERS. Well, the savings from the duty suspension certainly would be applied to North Carolina. I might just say, Congressman, in regard to the allegation that we are going to put $50 million into a plant in the Soviet Union, that is news to me. We are always evaluating possible joint ventures with a number of countries. We have a presence in 150 countries around the world.

Indeed, with the collapse of communism, if you will, we have, like any other pharmaceutical company, and indeed, a lot of other American industries have been exploring opportunities for joint ventures in the Eastern bloc.

My colleague, Mr. Wendt, I believe has a joint venture in Poland and possibly in other countries, so that these are always under consideration. But it is part of being a global company, and I can't be any more specific than that.

Mr. CRANE. Well, in your testimony, you indicated that if the suspension occurred, this would allow resources to be used for the construction of much needed new manufacturing capacity, and I was just wondering if you had any ballpark figures?

Dr. SANDERS. Well, that would be in North Carolina, and that would be part of it.

Mr. CRANE. Oh, this would all not be confined to North Carolina, you mean?

Dr. SANDERS. It would be confined to North Carolina, yes, sir.

Mr. CRANE. But you have no ballpark figure as to what kind of money——

Dr. SANDERS. Well, at the present time, Congressman, we are adding on a facility to our Zebulon complex at a cost of some $26 million.

Mr. CRANE. I see.

Dr. SANDERS. And additional facilities would be in that range.

Mr. CRANE. Now, my understanding is that SmithKline, Beecham has indicated that it would be disadvantaged by this proposed duty suspension and yet, my understanding is that there is a component, an ingredient, cimetidine, am I pronouncing it right——

Dr. SANDERS. Yes, sir.

Mr. CRANE [continuing]. That is not subject to import duties by virtue of being Puerto Rico based. And this gives SmithKline Beecham a competitive advantage, is that your assessment?

Dr. SANDERS. That's my interpretation. Indeed, their form 20–F that they filed with the SEC, shows they realized some $80 million in tax savings as a result of being based in Puerto Rico.

Now, to be perfectly honest, that tax savings is not all related to cimetidine. There are some other products they manufacture, but since cimetidine is such a large part of their product line, a significant portion of that would relate to cimetidine.

They pay, in effect, a 9-percent effective tax rate, I believe.

Mr. CRANE. Also, SmithKline Beecham has raised no objections with respect to a bill to suspend temporarily the duty on—and again I'm not sure of the pronunciation—famotidine?

Dr. SANDERS. Yes, sir.

Mr. CRANE. But this is an active ingredient in a product put out by Merck?

Dr. SANDERS. That's correct.

Mr. CRANE. And it competes in the same market, does it not, with your product?

Dr. SANDERS. Yes, sir.

Mr. CRANE. Have you any explanation why they have not raised objections to the duty suspension on the importation of that component?

Dr. SANDERS. Well, it's certainly inconsistent in light of the position that they have taken with Zantac and ranitidine. I have no explanation.

Mr. CRANE. What, in terms of the market breakdown, since Eli Lilly and Merrell Dow actively support your bill, what percentage of market share do you have in this broad area in contrast to SmithKline, or Lilly or Merck or any competitors?

Dr. SANDERS. Perhaps I could refer to this exhibit, Congressman, which I will submit for the record. I believe it's in the formal testimony under exhibit A. What it shows here is the number of new prescriptions, which is the best way to look at the market share.

If one looks at 1988, you will see that Tagamet had 34 percent of that market; Zantac had 44 percent; Carafate, the Marion Merrell Dow compound had 14; Axid had 1; and Pepcid had 7 percent.

Now, going on to 1990, our estimate in 1990 which is pretty close to that of 1989, it shows that Zantac stays constant, 44 percent in 1988, and 44 percent in 1990; Tagamet has shrunk from 34 to 26 percent of the new prescriptions; whereas Carafate has declined slightly; Axid has increased; and Pepcid has increased.

The only point being, Congressman, is that Zantac stays stable in these 3 years, but these other compounds, Axid, Carafate and Pepcid appear to be the reason that SmithKline has shrunk. So they are taking SmithKline's market share. We appear to be stable. We are not taking SmithKline's market share away from them.

Mr. CRANE. I see. Thank you, very much, Dr. Sanders.

Chairman GIBBONS. Mr. Russo.

Mr. RUSSO. Thank you, very much, Mr. Chairman.

Dr. Sanders, let me just say personally I think both your prices are too high and I can't wait until your patents on both products are gone so that we can get generic drugs and get them down much cheaper.

But having said that, if you were to apply the $7 to $9 million savings as you said, you would save what, $46 a month?

Dr. SANDERS. No, that would be 46 cents.

Mr. RUSSO. I'm sorry, 46 cents a month. That's right.

So as I figure it out you would be competing with Tagamet, you would be selling it for $78.33 and they would be selling it for $62.55?

Dr. SANDERS. Yes, sir.

Mr. RUSSO. So you are still much higher than they are?

Dr. SANDERS. Yes, sir.

Mr. RUSSO. Why would you have 60 percent of the market as you indicate if your product was so much more expensive? Why wouldn't the lower price make more people use Tagamet?

Dr. SANDERS. Well, I would like to say that we do have 60 percent of the market, but that's not quite correct. We have 52 percent of the dollar market and 44 percent of the new prescription market. When Zantac was introduced in 1983, Tagamet had 100 percent of the market. In 1990, we have 52 percent and SmithKline has about 26 percent.

The only reason that I can say we have done so well is the obvious acceptance by the prescribing physicians that Zantac is an outstanding drug. We believe it has superior efficacy and superior safety. And in the final analysis, it's the prescribing physician who determines that and it's not price that is effective here. Price is strictly secondary, when it comes to the care of the patient.

Mr. RUSSO. How many pills is that, the 30-day supply when the price is $78, is that one pill a day?

Dr. SANDERS. That is 60 pills.

Mr. RUSSO. That is 60 pills a month, so that is what it is.

Mr. RUSSO. Thank you.

Dr. SANDERS. Thank you, sir.

Chairman GIBBONS. All right, thank you, doctor.

Dr. SANDERS. Thank you, sir.

Chairman GIBBONS. Our next witness and last witness is Mr. Henry Wendt, from SmithKline Beecham, chairman of the board. Mr. Wendt, glad to have you here.

STATEMENT OF HENRY WENDT, CHAIRMAN OF THE BOARD, SMITHKLINE BEECHAM, ACCOMPANIED BY SEYMOUR M. SABESIN, M.D.

Mr. WENDT. Thank you, Mr. Chairman. Good afternoon.

I am acutely conscious of the fact that in the greater scheme of things you, Mr. Chairman, and your committee are examining many matters which make this affair seem rather minor. In that context, I would like to begin by thanking you for your time and your attention.

For me and for my company, I have to say this has become something of a matter of principle which is why we are here, but I think it is also a matter of principle with respect to the trade policy of the United States.

Mr. Chairman, I have brought with me my colleague, sitting to the left, Dr. Seymour Sabesin. Dr. Sabesin is a professor of medicine and director of digestive diseases with the department of medicine, at the Rush-Presbyterian-St. Luke's Medical Center in Chicago. He is an expert on ulcer disease and on ulcer therapy.

I have noticed with the previous witness there are a number of questions regarding the place of these two drugs in the practice of medicine and I think that Dr. Sabesin, with his excellent background and his expertise in ulcer disease, is well prepared to answer them.

I would like to submit his rather lengthy curriculum vitae for the record.

Chairman GIBBONS. All right, sir, without objection, it will be in the record.

[The curriculum vitae of Dr. Sabesin follows:]

CURRICULUM VITAE

SEYMOUR M. SABESIN, M.D.

EDUCATION

City College of New York, B.S., 1954
New York University School of Medicine, M.D., 1958

EXPERIENCE

January, 1986 - present	Dyrenforth Professor of Medicine; Director of Section of Digestive Diseases, Department Medicine, Rush-Presbyterian-St. Luke's Medical Center, Chicago, Illinois
1973 - 1985	Professor of Medicine; Director, Division of Gastroenterology; Director NIH-Sponsored Liver Disease Research Training Program, Department of Medicine, University of Tennessee Center for the Health Sciences; Attending Physician, University of Tennessee Hospitals; Consultant, Veterans Administration Hospital, Memphis, TN
1969 - 1973	Associate Professor of Medicine, Jefferson Medical College, Philadelphia, PA; Member, Gastrointestinal Division, Department of Medicine, Jefferson Medical College; Director, Electron Microscopy Laboratory, Department of Pathology, Jefferson Medical College; Assistant Director, Clinical Cancer Training Program, Jefferson Medical College; Attending Physician, Thomas Jefferson University Hospital; Consultant, Veterans Administration Hospital, Philadelphia, PA
1966 - 1969	Associate in Medicine, Harvard Medical School, Boston, MA; Assistant Physician, Massachusetts General Hospital, Boston, MA
1963 - 1966	Instructor in Medicine, Harvard Medical School, Boston, MA Research and Clinical Fellow, Massachusetts General Hospital and Harvard Medical School, Boston; Post-Doctoral Fellow, National Institutes of Arthritis and Metabolism (Gastroenterology), Massachusetts General Hospital (1963-1965)
1962 - 1963	Resident in Medicine, The New York Hospital-Cornell Medical Center, New York; Assistant in Medicine, Cornell Medical School, New York

1959 - 1962	Clinical and Research Associate, National Cancer Institute, National Institutes of Health, Bethesda, MD
1958 - 1959	Intern, State University of New York

SOCIETIES

Alpha Omega Alpha
American Association for the Advancement of Science
American Association for Cancer Education
American Association for the Study of Liver Diseases
American College of Physicians (Fellow)
American Federation for Clinical Research
American Gastrointestinal Association
American Heart Association
American Institute of Nutrition
American Society for Cell Biology
American Society for Clinical Nutrition
American Society for Experimental Pathology
Central Society for Clinical Investigation
Chicago Society of Gastroenterology
Council on Arteriosclerosis, American Heart Association
Massachusetts Medical Society
Southern Society for Clinical Investigation
International Association Study Liver Disease
International Association for Study Arteriosclerosis
Midwest Gut Club
Sigma Xi

HONORS

Alpha Omega Alpha
Recipient, Rorer Award of the American College of Gastroenterology, 1970 & 1971
Fellow, American College of Physicians
Fellow, Council on Arteriosclerosis, American Heart Association
Member, Veterans Administration Merit Review Board Gastroenterology, 1982
Member, International Association for the Study of Liver Diseases

ACADEMIC ACTIVITIES

Chairman, Research Committee, UTCHS
Chairman, Radiology Search Committee, College of Medicine
Chairman, Subcommittee on Research, Facilities, Space, Equipment, and Support Personnel, College of Medicine
Chairman, Hematology Search Committee
Member, Biomedical Science Committee, UTCHS
Member, Faculty Senate, UTCHS
Member, Dean's Committee, Veterans Administration Hospital

Mr. WENDT. The House conferees on H.R. 1594 agreed to hold public hearings on H.R. 3130 to examine whether the proposed relief adversely impacts domestic competition. In that regard I appreciate the opportunity to discuss with you what the Wall Street Journal and Fortune magazine have aptly described as the most intense competitive battle in the history of the pharmaceutical industry.

The major issue facing the subcommittee this afternoon, as I understand it, is pretty straightforward: is Tagamet, our form of cimetidine, a competitor of Zantac, Glaxo's form of ranitidine?

On that point there can be no debate and indeed, my colleague, Dr. Sanders, has just testified that we are competitors. As chairman of the board of SmithKline Beecham, I can state with absolutely no reservation that Glaxo's ranitidine is our major competitor in every country of the world, and especially in the United States of America, which, as you know, is by far the largest and most competitive pharmaceutical market.

But the purpose of today's hearing, of course, is to see the evidence. In preparation for this hearing today, we have gone back and we have looked at what the financial and medical press have said about this competition since before ranitidine came onto the U.S. antiulcer market in July of 1983.

These reports are convincing, Mr. Chairman. They are contained in this overly large binder, and I would like to submit them for the record.

Chairman GIBBONS. We had better look at that, the printing might be too high.

Mr. WENDT. It's expensive, I agree, but it's all done and paid for.

Chairman GIBBONS. Without objection—I'm not sure this record is going to be very widely read and I might want to save the Government some money, so we will take that under advisement.

Mr. WENDT. All right, sir, I will leave that in your hands.

Chairman GIBBONS. Leave it with us and we will make sure it won't get lost.

Mr. WENDT. In any event, I will be happy to summarize it for you.

These exhibits demonstrate beyond any doubt that ranitidine and cimetidine have been unrelenting head-to-head competitors in the United States from 1983 until today and that this competition will continue unabated.

In my attachment, you will find the Wall Street Journal's description of cimetidine versus ranitidine and I quote, "One of the pharmaceutical industry's biggest marketing wars ever, a battle of billion dollar ulcer drugs."

In fact, as early as 1983, Fortune magazine had characterized this competitive struggle as the ulcer holy war. In today's climate a bad choice of words.

The attachment also includes quotes from many other articles. These quotes, Mr. Chairman, are all from third party, impartial sources.

But far more compelling proof than that is indeed found in Glaxo's own actions. From the moment of Zantac's launch in the United States, Glaxo compared its product to Tagamet, our brand of cimetidine. Previous testimony has already referred to the letter

from the Food and Drug Administration of June 1986, demanding that Glaxo stop describing ranitidine as superior to cimetidine in its advertisements and in its medical journals.

The FDA said, Glaxo's competitive claims against cimetidine were untrue. The FDA letter to Glaxo said, and I quote,

> All of these points have been discussed repeatedly with your firm and as expressed in our letters of February 13, 1985, and September 11, 1985.

In other words, Glaxo has tried in every way it could to convince doctors that ranitidine should be used in place of cimetidine. That, Mr. Chairman, I submit is a classic definition of competition.

In this keenly competitive environment it is clear that granting duty suspension for ranitidine will operate to the detriment of SmithKline Beecham.

If Glaxo is awarded duty suspension it will obtain a windfall estimated at $39 million, an estimate put forth by Senator Helms from the State of North Carolina and that money will come directly from the Treasury of the United States.

This is money that will allow Glaxo to further penetrate this market, where it already holds approximately a 60 percent share of the H–2 antagonist market. Whether that windfall will be used directly or indirectly for wider advertising or an increased sales force, the result is the same: competitive disadvantage to SmithKline Beecham and competitive advantage to Glaxo.

Here it is important to note that you would not be helping a struggling company. Glaxo may well be the richest and most profitable of all the world's pharmaceutical giants. Zantac, alone, sells at nearly the rate of $2.6 billion a year. Glaxo's corporate profits are more than $2 billion a year. And just last Friday, the Times of London pointed out that Glaxo has, and I quote, "A comforting 1 billion pounds in cash." At current rates that is about $1.85 billion of cash for whatever need comes to mind.

This profitable company also owns the patent on ranitidine, as Dr. Sanders has said. It could well afford to build a U.S. plant to produce this product if it chooses because it has more than $4 billion set aside for capital projects in the next 4 years.

As you know, duty suspension for ranitidine has been already subjected to congressional scrutiny. In fact, this subcommittee rejected the request last year. The Senate Finance Committee did not accept it.

The chairman of that committee, Senator Bentsen, said during the Senate floor debate, and I quote once again,

> One of the good reasons for opposing an amendment such as this where it is controversial and objected to is the effect it might have on the new round of trade agreements in the GATT.
>
> If we are going to make tariff concessions that affect U.S. producers we should do it as part of those multilateral negotiations and we ought to be getting something for that concession.

Now, in his testimony, Dr. Sanders made quite a point of the fact that Tagamet is manufactured in Puerto Rico and that, indeed, is the case. We have been manufacturing as a company in Puerto Rico for nearly 20 years and are proud to do so. We employ over 1,000 people in Puerto Rico. And we are a good corporate citizen in Puerto Rico as we are in Philadelphia and elsewhere in the United States of America.

We operate under the 936 tax legislation that was passed and endorsed repeatedly by this Congress. I regard that, frankly, as an irrelevancy. Puerto Rico is part of the United States of America as far as customs duties are concerned, and therefore, where in the United States we make Tagamet seems to me to be something of a red herring, if I may say so.

Mr. Chairman, you and the other members of this subcommittee, have more pressing business facing you this afternoon when this hearing is over. From what we hear in the news, Congress will be hard pressed to find the money to keep Medicare and Medicaid afloat, to finance NIH and FDA and to fund programs for the poor and the elderly. Balanced against these stark facts, you now have before you the request that the Treasury not collect $39 million that Glaxo would owe for imported ranitidine.

I respectfully submit that that request does not merit consideration in light of our national priorities.

Mr. Chairman, thank you, very much. I submit my full statement for the record.

Thank you, sir.

[The prepared statement and attachment follow:]

Testimony of Henry Wendt
Chairman of the Board
SmithKline Beecham
Before the
Subcommittee on Trade
Committee on Ways & Means
U. S. House of Representatives
Hearing on H.R. 3130
To Suspend Temporarily the Duty on Ranitidine Hydrochloride
Monday, September 24, 1990 - 4:00 p.m.

Mr. Chairman and Members of the Subcommittee.

The House Conferees on H.R. 1594 agreed to hold public hearings on H.R. 3130 to examine whether the proposed relief adversely impacts domestic competition. In that regard, I appreciate the opportunity to discuss with you what the Wall Street Journal and Fortune magazine have aptly described as the most intense competitive battle in the history of the pharmaceutical industry.

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. Is Tagamet, our form of cimetidine, a competitor of Zantac, Glaxo's form of ranitidine?

On that point there can be no debate. As the Chairman of the Board of SmithKline Beecham, I can state with absolutely no reservation that Glaxo's ranitidine is our major competitor in every country in the world, especially the United States, which as you know, Mr. Chairman, is by far the largest and most competitive pharmaceutical market.

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In preparation for this hearing, we have gone back and looked at what the financial and medical press have said about this competition since before ranitidine came on the U.S. anti-ulcer market in July of 1983.

These reports are convincing, and I would like to submit them for the record. I would also like to submit a sampling of the Glaxo promotional materials. Together, these exhibits demonstrate beyond any doubt that ranitidine and cimetidine have been unrelenting, head-to-head competitors in the United States from 1983 until today -- and this competition will continue unabated.

In my attachment you will find the Wall Street Journal's description of cimetidine versus ranitidine as (quote) One of the pharmaceutical industry's biggest marketing wars ever -- a battle of billion-dollar ulcer drugs (end quote).

In fact, as early as 1983, Fortune magazine had characterized the initial competitive struggle as the Ulcer Holy War. The attachment also includes quotes from many other articles about this intense competition -- from the New York Times, the Economist, Business Week and many other sources.

These quotes, Mr. Chairman, are all from impartial third parties. But for more compelling proof that we are indeed head-on competitors, let's look at Glaxo's own actions.

From the moment of Zantac's launch in the United States, Glaxo compared its product to Tagamet, our brand of cimetidine.

Moreover, in June of 1986, the Food and Drug Administration demanded that Glaxo stop describing ranitidine as superior to cimetidine in its advertisements in medical journals. The FDA said Glaxo's competitive claims against cimetidine were untrue. And the agency pointed out that Glaxo had been running these unfair comparison ads for years.

The FDA letter to Glaxo said: (quote) All of these points have been discussed repeatedly with your firm and as expressed in our letters of February 13, 1985 and September 11, 1985. (end quote)

In other words, Glaxo has tried in every way it could to convince doctors that ranitidine should be used in place of cimetidine. I submit, Mr. Chairman, that that is a classic definition of competition.

In this keenly competitive environment, it is clear that granting duty suspension for ranitidine will operate to the detriment of SmithKline Beecham.

If Glaxo is awarded duty suspension, it will obtain a windfall estimated at $39 million (per letter from Sen. Helms) from the Treasury of the United States. This is money that will allow Glaxo to further penetrate this market where it already holds approximately a 60 percent share.

Whether that windfall will be used directly or indirectly for wider advertising or an increased sales force, the result is the same -- competitive disadvantage to SmithKline Beecham and competitive advantage to Glaxo.

And here it is important to note that you would not be helping a struggling company.

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The Chairman of that committee, Senator Bentsen, said during Senate floor debate (and I quote):

"One of the good reasons for opposing an amendment such as this, where it is controversial and is objected to, is the effect this might have on the new round of trade agreements in the GATT. If we are going to make tariff concessions that affect U.S. producers, we should do it as part of those multilateral negotiations, and we ought to be getting something for that concession."

Mr. Chairman, you and the other members of the subcommittee have more pressing business facing you this afternoon when this hearing is over.

From what we hear on the news, Congress will be hard pressed to find the money to keep Medicare and Medicaid afloat, to finance NIH and FDA and to fund programs for the poor and the elderly.

Balanced against those stark facts, you now have before you the request that the Treasury not collect $39 million that Glaxo would owe for imported ranitidine.

I respectfully submit that that request does not merit consideration in light of our national priorities.

Thank you, Mr. Chairman. I submit my full statement for the record.

Documentation of Competition: Zantac v. Tagamet

Since the introduction of Glaxo's anti-ulcer drug, ranitidine (Zantac), to the market in July of 1983, the intense competition between this product and SmithKline Beecham's anti-ulcer drug, cimetidine (Tagamet), has been chronicled by a variety of medical and financial publications. The following are selected excerpts:

March 16, 1990, Pharmaceutical Business News: "Glaxo's Zantac, meanwhile was been powering ahead too: it is the world's single best-selling drug with sales of around $2 billion last year, has won what was essentially a marketing battle with Tagamet hands down...."

March 16, 1990, The Independent: "Zantac's main rival Tagamet is 40 percent cheaper, and its manufacturer SmithKline Beecham says that for the first time since Zantac was launched in 1982, the price differential is starting to tell."

January 27, 1990, The Economist: "Britain's Glaxo turned itself into a leading international drug firm after it spent lavishly to promote Zantac, an anti-ulcer pill which became the world's best-selling drug, even though it was only a slight improvement on Tagamet."

November 6, 1989, Fortune: "Paul Girolami, Glaxo's chief executive from 1980 to 1986.....orchestrated a full-scale attack on the American market. His goal: to overtake SmithKline's best-selling Tagamet on its home ground."

August 3, 1989, The Wall Street Journal: "But Glaxo Holdings PLC has exploited the problem to help vault its own ulcer drug Zantac ahead of Tagamet in one of the pharmaceutical industry's biggest marketing wars ever -- a battle of billion dollar ulcer drugs."

May 29 1989, Chicago Tribune: "The document did not give market-share estimates for Tagamet's key competitors, Zantac from Glaxo Holdings and Pepcid from Merck & Co."

May 22, 1989, Business Week: "The company (Glaxo) beat back competition from Tagamet, SmithKline Beckman Corp.'s anti-ulcer drug."

April 4, 1989, Financial World: "...Glaxo waged its classic battle against SmithKline's Tagamet. Zantac and Tagamet were similar, though Zantac was a bit more potent....."

March 15, 1989, Reuters: "...it (Zantac) cost 40 per cent more than rival Tagamet, made by U.S. group SmithKline, but still went on to lead the market."

March 15, 1989, Reuters: "Analysts have said Zantac could suffer when its main competitor, Tagamet...goes off-patent in the U.S. in 1992."

January 25, 1989, Chemical Week: "Zantac was promoted as having fewer side effects than Tagamet and fewer complications when used in combination with other drugs."

October 12, 1988, Focus: "GASTROINTESTINAL WARS:..Zantac has gained a couple of market advantages on Tagamet."

October 10, 1988, Business Week "HOW GLAXO'S EAGER BEAVERS CHEWED UP TAGAMET'S LEAD": "SKB is fighting Glaxo's fire with its own. A new Tagamet offers the same daily dosage requirement as Zantac."

May 17, 1988, Financial World: "And when SmithKline's competing Tagamet comes off patent in just six more years, it is bound to spawn a slew of generic Zantac-like clones."

May 9, 1988, The Pink Sheet: "While Zantac growth continues, SmithKline's Tagamet is beginning to taper a bit....'The anti-ulcer market is one of the largest and most aggressively marketed categories in pharmaceuticals,' PDS (Pharmaceutical Data Services) observed."

April 18, 1988, The Pink Sheet: "In recent months, SmithKline has increased the size of its own sales force and signed on Dupont's physician detail force to comarket Tagamet to counter Zantac's preeminance in the market."

April 1, 1988, The Wall Street Journal: "Glaxo Inc., following its chief rival in the anti-ulcer prescription drug market, will launch a television advertising campaign aimed at antacid users....Zantac and Tagamet dominate the market for drugs of their type...."

December 23, 1987, The Wall Street Journal: "But the SmithKline move and Glaxo's response sharpen the companies' acute rivalry and mark the latest in a series of co-marketing and cross-licensing agreements in the pharmaceutical industry, largely reflecting intensifying competition."

March 23, 1987, The Pink Sheet, "ZANTAC MAY SUPERSEDE TAGAMET IN U.S. ANTI-ULCER DOMINANCE IN 1987...": "Zantac and Tagamet are now running neck and neck in the U.S. retail market, according to PDS sales figures."

November 18, 1986, Financial Times: "SmithKline's position is now threatened by Glaxo, which a month ago claimed to have edged into the top spot with its own hugely successful drug Zantac. The Glaxo drug, also an ulcer treatment, imitates the Tagamet principle...."

October 20, 1986, The Pink Sheet: "Merck's Pepcid will join Tagamet-Zantac Fray in the anti-ulcer market with its upcoming mid-November launch."

September 2, 1986, Financial World: "The product essentially driving Glaxo is Zantac, a $900 million anti-ulcer drug that has been fighting head-to-head with SmithKline's own money machine, Tagamet...."

June 9, 1986, The Pink Sheet: "Glaxo's claims of Zantac superiority to Tagamet in recent letters to Hawaii and California Medical Therapeutics and Drug Advisory Cmtes. was criticized by the FDA in a four page notice to the firm."

May 1, 1986, The Wall Street Journal: "The approval will intensify competition between Tagamet and Glaxo Holdings PLC's Zantac anti-ulcer medicine."

December 3, 1984, Forbes: "...Paul Girolami, chief executive of Glaxo Holdings PLC. He promises some real competition for SmithKline's Tagamet...."

May 29, 1984, Financial Times: "The struggle, for dominance of the U.S. market for anti-ulcer drugs, which has already brought Glaxo Holdings across the Atlantic to challenge SmithKline will not become any less fierce in the next five years, but will present new challenges to the gladiators."

September 19, 1983, Fortune, SMITHKLINE'S ULCER MEDICINE 'HOLY WAR': "A success in Europe, Zantac has just come to market in the U.S. and the competitive struggle shaping up will undoubtedly give some SmithKline executives stomach pains."

April 16, 1983, Financial Times: "Much of the excitement about Glaxo has centered on its new anti-ulcer drug Zantac, and what the drug might do to spearhead its attack on the important U.S. market and on SmithKline's Tagamet...."

Chairman GIBBONS. Yes, sir, without objection, your full statement will be included in the record, and that large publication that you had there we will take a look at it. We may print it and we may not. It just depends on what it is going to cost.

Mr. Schulze.

Mr. SCHULZE. Thank you, Mr. Chairman.

I might have a suggestion that if it is too lengthy to print, perhaps we can just make sure that Commerce has a copy of it, because they said they were looking into this. So that we could just run off a copy in the Xerox machine and make sure that they have it.

Chairman GIBBONS. Sure.

Mr. WENDT. We would be happy to supply Commerce with a copy.

Mr. SCHULZE. Oh, fine. That will save the subcommittee a little money.

Mr. WENDT. We will supply them several copies and save the Government a little money.

Mr. SCHULZE. Mr. Wendt, I am pleased to have you before the committee and I don't want to drag this out. I just want to ask you one question.

I know that Dr. Sanders said that the products were competing products. However, on page 4 and 5 of the testimony it states or it has a discussion of the technical difference between Tagamet and Zantac, and I just wonder whether you wanted to reinforce that similarity or whether you have any comments on the technical differences, and/or similarities between Zantac and Tagamet?

Mr. WENDT. Chemically the two compounds are similar but different in detail and they represent, therefore, different molecules.

They both are in the class of H-2 antagonists and I think the definition is best put in the context of how physicians look at these two products. After all it is they who decide which patients should receive Tagamet and which should receive Zantac.

If I may, Congressman, I would like to ask Dr. Sabesin, sitting to my left, to respond to that question?

Mr. SCHULZE. Certainly.

Dr. SABESIN. Congressman, thank you. Thank you, Mr. Wendt. My purpose in appearing here is to give you my objective opinion about the relative efficacy and safety of the two drugs in question. I do this from the perspective of a professor of medicine who has been involved in the clinical evaluation of these compounds and other compounds for approximately 20 years, as well as a practicing physician and academic teacher.

My view of these drugs is that essentially from the point of view of the therapy of patients with peptic ulcer disease that they are virtually indistinguishable. And this opinion, over the past several years, has been reinforced by the actions of physicians around the country and more specifically hospital formulary committees, who tend to switch from one drug to another based on the contracts which they can obtain from the competing pharmaceutical companies based on price.

In other words, one year a hospital formulary may decide to use one H-2 receptor antagonist, perhaps cimetidine, and the following year they may switch to a competing H-2 receptor antagonist, per-

haps Zantac or perhaps famotidine Pepcid. But the long and short of this is that the hospital formulary committees, and increasingly large number of physicians feel that these drugs therapeutically are the same, and therefore, may decide to prescribe the drugs based on price, cost considerations, rather than any substantial differences between the drugs, in regard to their therapeutic efficacy or their safety.

Therefore, I feel that the drugs and probably the other drugs in the same therapeutic class are virtually indistinguishable. Of course, there are slight differences between the drugs from the pharmacological point of view and perhaps slight differences from other points of view. But when the great mass of clinical literature from around the world is looked at objectively, there is virtually nothing to choose from between this therapeutic class of drugs. Again, I state this as a physician who has been involved with all of the companies in question, as an independent investigator and teacher, and have worked very closely with all the companies at issue.

Thank you.

Mr. SCHULZE. Thank you, sir.

Chairman GIBBONS. Mr. Pease.

Mr. PEASE. Thank you, Mr. Chairman.

I appreciate your statement, Mr. Wendt. I would like to state for the record that although my wife's maiden name is Wendt, I have no conflict of interest here, and I am a simple seeker after the truth. [Laughter.]

Mr. WENDT. Obviously a man of great good taste, Congressman.

Mr. PEASE. I would second that; it's certainly true.

We have a conflict in the testimony here. You mentioned the value of this duty suspension as $39 million and Dr. Sanders mentions the figure of $7 to $9 million. Can we clarify who is correct about that?

Mr. WENDT. The source of the $13 million that I quote in my testimony is from a letter written by Senator Helms to Senator Dole on this very subject some months ago.

Mr. PEASE. You say, $13 million or $39 million?

Mr. WENDT. $13 million times 3 years.

Mr. PEASE. Oh, I see, all right, so that the difference is not really that great.

Mr. WENDT. It adds up.

Mr. PEASE. Well, I remember the old statement that a Senator from Illinois once said, "A billion here and a billion there, pretty soon it adds up."

A million dollars gets lost among the asterisks I suppose.

No, I would like to point out for the record that I am not serious about that last statement either. But essentially aren't we being asked to simply intervene in a competitive battle between two corporations? Why should we be involved in this anyhow?

Mr. WENDT. Well, I think that's a very good question, Congressman. And why are we all here? We are here because our competitor has asked for a duty suspension and it's my understanding that in past practice, duty suspensions are granted when a product cannot be made in the United States either by virtue of technology

or license or other considerations such as that, and when a U.S. competitor is not harmed by the duty suspension.

In this case, the product could be made in the United States, as Dr. Sanders said in his testimony. And I, as a direct competitor, involved in what I just testified as the greatest competitive battle in the history of the pharmaceutical industry, object on competitive grounds. I would be perfectly pleased not to be here, but that's why we are all here.

Mr. PEASE. Surely.

What about the other companies in this field? You have not objected to some of their duty suspensions?

Mr. WENDT. Well, Dr. Sanders mentioned that famotidine, which is a product marketed by Merck, here in the United States, has applied for a duty suspension. That legislation, as I understand it, is not active.

We have not yet taken a position. We are keeping our powder dry, you might say, on that issue. Indeed, we reserve the option to object if we so decide. So that issue lies before us.

With respect to the product, Carafate, which is the third product down on the chart, to your left, that is not an H-2 antagonist, that is not a product with the same pharmacology as Zantac and Tagamet and famotidine and the Lilly product, nizatidine. They are all H-2 antagonists and Carafate is not. So we did not object in the case of Carafate.

Mr. PEASE. I see.

According to some information, Lilly and Marion Merrell Dow support this bill. Is that correct, as far as you know?

Mr. WENDT. I heard that to some surprise this afternoon. As far as I know, that is not the case. There is a difference between not opposing and supporting. My information is that they are not opposing. But I don't put that in the category of support, but I think those companies had best speak for themselves.

Mr. PEASE. Very well, thank you, sir.

Mr. WENDT. Thank you, Congressman.

Chairman GIBBONS. Mr. Crane.

Mr. CRANE. Thank you, Mr. Chairman.

Chairman Wendt, were those figures essentially confirmed by your figures on market share that Dr. Sanders gave us? I think he quoted 1987 and 1990 figures and their market share was 44 and yours 34 in 1987; and theirs is 44 today and yours is down to 26?

Mr. WENDT. They define the market differently than we do, sir, so therefore, the percentages are different. They have included, as I just said, Carafate in the market. We look at the H-2 antagonists, the four H-2 antagonists which are currently on the market, which, as Dr. Sabesin testified a few minutes ago, essentially are interchangeable in terms of their clinical application, as the market. So if you eliminate Carafate you will get a higher percentage for Zantac than 44 and you will get a higher percentage for Tagamet than 26.

Mr. CRANE. But has there been a decline, from your perspective, in your portion of the total market over the last few years?

Mr. WENDT. Yes. In that sense, the figures are absolutely correct.

Mr. CRANE. The reason I asked that is that you passed out some documentation of competition and there is a quote here included

from Reuters dated March 15, 1989, that Zantac cost 40 percent more than rival Tagamet made by U.S. group SmithKline but, in spite of that it still went on to lead the market. Then the Independent, you have a quote here, March 16, 1990, that

> Zantac's main rival, Tagamet, is 40 percent cheaper and its manufacturer, SmithKline Beecham says that for the first time since Zantac was launched in 1982, the price differential is starting to tell.

Starting to tell in your favor?

Mr. WENDT. Well, it is really hard to say but I would defer again to Dr. Sabesin's testimony that the medical profession now views these H-2 antagonists as being essentially interchangeable in their clinical application, so that the greatest point of differentiation often is price, and that leads to the decision.

Do you want to comment further, some more on that?

Dr. SABESIN. Just to briefly reiterate. I think there are many reasons why physicians have and maintain certain prescribing habits, which may or may not be related to perceptions of the efficacy or to new data about the efficacy of a drug. Physicians, like others, fall into certain habits. They are influenced by marketing, by the sales force, and by many other peripheral issues.

But if we separate out all of those considerations and I believe look, just very objectively, at the published data regarding efficacy and now, safety of the drugs as a class that we are discussing, I would once again maintain that there is very little to choose between the drugs.

Again, this has been substantiated by the switches which occur from hospital-to-hospital, year-by-year, and by physicians, sometimes from patient-to-patient.

And, therefore, cost considerations become more and more important and I would suggest that if it weren't, in large measure, a question of custom or habit that the physicians might reflect more on the price differentials and they might change their prescribing habits. This is true for the class of drugs that we are dealing with today as well as many other therapeutic categories of drugs.

Mr. CRANE. So basically you are increasingly optimistic about escalating your market share, is that right, because of the price differential?

Dr. SABESIN. I think that this becomes a sales and a marketing issue more than a medical issue and it depends, therefore, on the skills, so to speak, of the companies to market their drugs appropriately and, therefore, to influence physician-prescribing habits and to get them to change.

It's very difficult to get physicians to change.

Mr. CRANE. I thank you.

Dr. SABESIN. Both of the drugs are wonderful drugs, and therefore, it is hard to get them to switch.

Mr. CRANE. Thank you, very much.

Dr. SABESIN. Thank you, Congressman.

Chairman GIBBONS. Mr. Russo.

Mr. RUSSO. Thank you, Mr. Chairman.

What we are charged to do, Mr. Wendt, is to figure out whether there is any injury suffered as a result of this duty suspension. If

in fact, there is an injury and it creates a competition problem then we ought to look at it.

But if I am to understand Dr. Sanders, if he applied the entire $7 to $9 million and maybe even the $13 million you are talking about, the price of the drug, even if we took off the 79 cents versus the 46 cents, your product is still something like almost $16 or $15.50 cheaper than their product. So in terms of injury from price, the injury, if they applied all of it to the price, there would not be any injury.

Mr. WENDT. Correct.

Mr. RUSSO. So then we have to decide whether or not there is price competition and on the price side, it fails there. And the other argument is why does a product which would sell at $78 and yours at $62.55, have 46 percent of the share and you have 34 percent of the share?

Mr. WENDT. Roughly.

Mr. RUSSO. I mean some people are willing to pay $15 more for Zantac, obviously for whatever reasons they decide, right? I'm just trying to figure out where the injury is here, and I don't see the injury in terms of price. They are still going to sell for more than yours. Obviously you have the best competitive edge that anybody can have. Your $15—as I understand the free market system in this country—your $15 and even if he applies the $9 million there, you are $15.50 cents cheaper a month. That is not peanuts for a lot of people who buy this product.

Mr. WENDT. Very well put. In response, Congressman, let me just point out that price is not the only form of competition.

Mr. RUSSO. I understand that but that is one of the biggest.

Mr. WENDT. It is a big element, but in this business as in other businesses, marketing clout also is a factor. My concern is that the money saved will be applied against us in promotion and marketing clout.

Mr. RUSSO. Yes, but you have a 25-percent price differential where you can use the difference and clobber them as much as you want in terms of advertising. You have more to spend because you should be selling more and your product is cheaper.

Mr. WENDT. We have less to spend because our product is cheaper. They have more to spend because they have a more expensive product and they want to——

Mr. RUSSO. Out of the $78, how much does Zantac cost them to make; and out of the $62, how much does it cost you to make Tagamet?

Mr. WENDT. You will have to ask Glaxo about Zantac.

Mr. RUSSO. OK.

Mr. WENDT. But the total marketing cost as well as the cost in research and development are considerable. And it is the marketing costs, it is the marketing expenses that I am concerned about. This is a marketing battle as Dr. Sabesin just said.

Mr. RUSSO. I understand that, but——

Mr. WENDT. The number of salesmen, the advertising, the promotion, the weight of marketing that is put behind these products—and let me say that Glaxo is a very competitive company.

Mr. RUSSO. Well, I don't think that SmithKline takes a back seat to anybody when it comes to competition. But I also noticed that SmithKline does most of its work in Puerto Rico?

Mr. WENDT. That's right.

Mr. RUSSO. And I am very familiar with section 936 and it gives a tremendous advantage to those companies who make their products in Puerto Rico.

Mr. WENDT. It certainly does.

Mr. RUSSO. OK, let me ask you this. What kind of a benefit does your company get under section 936 a year?

Mr. WENDT. We get a substantial benefit from operating in Puerto Rico and that helps us to keep the price of Tagamet down.

Mr. RUSSO. How much is it—$7 to $9 million a year or is it more than $7 to $9 million a year?

Mr. WENDT. That's a little hard to calculate because we make a lot of products in Puerto Rico in the same factories, but it is a substantial benefit, and that is one reason why Tagamet is priced at a lower level.

But our competitor manufactures in Singapore, which is a very attractive, from a tax point of view, manufacturing location as well.

Mr. RUSSO. See, my personal view is that we ought to get rid of all duty suspensions and get rid of section 936 and let you fellows compete head on, on a level playing field. Unfortunately we have duty suspensions, we have section 936 and we have to sit up here and try to balance and juggle everything especially when a company is trying to create jobs and do business in a State in our country. You know, we want to foster jobs, foster employment and foster expansion.

Now, I wish they would all come to Chicago and build it all in Chicago, but unfortunately they have decided to go to North Carolina and you have decided to go to Puerto Rico.

Mr. WENDT. Well, if Glaxo decides to build a manufacturing plant, then maybe you can attract them to Chicago. I mean that decision lies ahead of them.

Mr. RUSSO. OK, thank you, Mr. Wendt.

Mr. WENDT. Thank you, sir.

[The following was subsequently received:]

SmithKline Beecham

Henry Wendt
Chairman of the Board

October 12, 1990

Supplement to the Testimony of Henry Wendt, September 24, 1990
Subcommittee on Trade, House Ways and Means Committee

Questions were raised by Representatives Pease and Russo dealing with the involvement of Congress in this issue, price competition and the advantage of manufacturing a pharmaceutical product in Puerto Rico. I would like to amplify my response to those questions.

1) During questioning, Rep. Pease said: "But essentially aren't we being asked to simply intervene in a competitive battle between two corporations? Why should we be involved in this anyhow?

The Congressman's question goes to the essence of this issue. The Subcommittee has been unduly imposed upon due to the persistence of Glaxo in attempting to obtain a $39 million windfall. As you know, Glaxo's effort to prove its case before the appropriate committee and at the appropriate time was unsuccessful.

Glaxo has not demonstrated a need for the $39 million concession it is asking from the U.S. Treasury, and more importantly, it has not offered the Congress any benefit -- such as a lower price to the patients.

One Franklin Plaza, PO Box 7929, Philadelphia, PA 19101. Telephone (215) 751 4211. Fax (215) 751 7043.

In fact, Glaxo offers none of the traditional reasons given for requesting duty suspensions. Glaxo is not trying to import a licensed product. It owns the patent on ranitidine. The chemical is not difficult or impossible to produce in the United States, and Glaxo's patent gives it every right to do so. Dr. Sanders conceded in his testimony that ranitidine could easily be made in this country.

Glaxo itself is not struggling or in need of taxpayer support. It is a rich company, with nearly $2 billion in cash. It holds a commanding position, with nearly 60 percent of the U.S. H2 antagonist ulcer market.

And Glaxo charges the highest price of any of the H2 antagonist ulcer drugs, including the two newest products that were introduced subsequent to ranitidine (Zantac). Although Dr. Sabesin and other experts in gastroenterology have pointed out that there is little therapeutic difference between these drugs, patients who take ranitidine pay a much higher price. The U.S. government is one of those purchasers that pays the high premium price.

Of course, Rep. Pease is right. At a time when the elderly of this country are bombarding their representatives about the cuts in Medicare, why should Congress be spending its valuable time on this duty suspension controversy?

And when the Congress, through the budget summit and succeeding resolutions, has targeted the pharmaceutical companies for $1.6 billion in Medicaid cost reduction over five years, why should it at the same time hand a $39 million tax break to one of the richest and most successful pharmaceutical companies?

2)Rep. Russo stated: "...You have a 25 percent price differential where you can use the difference and clobber them

as much as you want in terms of advertising. You have more to spend because you should be selling more and your product is cheaper."

There are two answers to the Congressman's statement. The first is that it is Glaxo, the company with the higher price and the dominant market share, that is asking Congress to suspend the duty. Glaxo is the company with more revenues for promotion, advertising, physicians' conferences and support of a large sales force. In short, it has more money to spend than its competitors.

The second point is that a physician's decision to write a prescription is rarely driven by price. Industry studies have shown a strong correlation between "detailing" (the sales calls to doctors' offices) and prescribing patterns. The prescribing decision is based on the physician's medical knowledge and the advertising/promotion efforts of individual companies, and is not normally decided by the physician based upon price. The patient who pays for the product is, of course, sensitive to price, but by that time the selection/decision has already been made by the doctor.

We can further illustrate the point by noting that Glaxo 's Zantac dominates in the physicians' office market where price is a minor factor. In the hospital market, where the decision-maker is extremely price-sensitive, SmithKline Beecham's Tagamet has increasingly been adopted as the H2 antagonist of choice. Hospital newsletters attesting to that fact are being submitted for the record.

If Congress should decide to intervene in a competitive marketing battle by giving a special tax break to one company, it should be aware of the value of the windfall that would be granted and the adverse affect that action would have on the domestic manufacturer, SmithKline Beecham.

In a market driven by the number of "details" -- or sales calls -- to physicians' offices, a $39 million gift to Glaxo would provide a tremendous advantage. Currently, the four companies that sell H2 antagonists in the U.S. market make a total of 300,000 detail calls each month to physicians' offices.

The industry places the cost of each detail at $40-50, and it is generally agreed that a higher number of details for one company will lead to higher market share.

Our study of the potential effect of a taxpayer's windfall to Glaxo indicates that a duty suspension of $13 million a year would pay for 22,000 to 28,000 additional details for ranitidine (Zantac) each month. Based on past experience, that higher level of detailing could mean a one point market share loss to SmithKline Beecham's Tagamet in the first year, meaning a loss in dollars of $25 million. Tagamet share would continue to decline in years two and three to an estimated level by 1993 of 2.5 market share points below where it would have been without the additional Glaxo promotion.

The cumulative impact over the period 1991-93 could be lost sales of well over $100 million to SmithKline Beecham.

3) Rep. Russo also stated: "...I also noticed that SmithKline does most of its work in Puerto Rico...and I am very familiar with Section 936 and it gives a tremendous benefit to those companies who make their products in Puerto Rico."

As I stated before, SmithKline Beecham is proud of its operations in Puerto Rico and the role they have played in building a strong economy in the Caribbean. Puerto Rico is a Commonwealth of the United States, and the island is considered part of the United States for customs purposes as well as other purposes. Puerto Ricans are U.S. citizens and they proudly serve in the U.S. Armed Forces. Puerto Rico is a key strategic

part of our defense establishment, with its Naval Station, Roosevelt Roads, one of the most important in the Atlantic Naval Force.

There are tax benefits to companies operating under Section 936. But these pale in comparison to the benefits enjoyed by Glaxo, which produces all of its ranitidine in Singapore for the U.S. retail and hospital markets. Singapore is considered among the most advantageous tax haven sites in the world, if not the very best.

The average manufacturing wage in Singapore is $2.67 an hour. In Puerto Rico, it is $5.56 (SmithKline Beecham employees have a higher average wage). After the credit the United Kingdom allows for taxes paid in Singapore, Glaxo ends up with an effective tax rate of 4 percent for the production of ranitidine in Singapore. However, SmithKline Beecham and other domestic companies pay a 10 percent tollgate tax on earnings repatriated from Puerto Rico under Section 936.

Clearly, Singapore offers more tax advantage than Puerto Rico. And U.S. citizens receive no economic benefit from Singapore investment, unlike the substantial economic and security benefits the U.S. mainland derives from Puerto Rico -- the "economic beacon" in the Caribbean.

Moreover, if one adds the 3.7 percent U.S. duty rate on ranitidine to Glaxo's low 4 percent tax rate because of its Singapore production site, its total tax and duty rate of 7.7 percent is still less than Puerto Rico's 10 percent tollgate tax.

4) To summarize:

. Glaxo has made no case regarding the need for this duty suspension, while the needs of the U.S. Treasury for every available dollar are obvious.

. Congress, while targeting the pharmaceutical companies for $1.6 billion in Medicaid cost reduction, would be awarding a

$39 million giveaway to one of the richest drug companies.

. Nothing prevents Glaxo from building a plant in the United States right now to produce this chemical and thus pay no duty.

. Granting of the duty suspension would give Glaxo, the dominant company in the H2 ulcer market and producer of the most expensive medicine, $39 million to use to take an even higher share of the market.

. Glaxo already has the world's best tax advantage by producing ranitidine in Singapore.

October, 1990

[ADDITIONAL MATERIAL SUPPLIED WITH THIS SUPPLEMENTAL STATEMENT IS BEING RETAINED IN THE COMMITTEE FILES.]

Chairman GIBBONS. All right, this concludes the hearing. We thank you Mr. Wendt, and Doctor Sabesin.

The record will remain open until the close of business on Friday, the 28th of September, this year.

Thank you, very much.

Mr. WENDT. Thank you, Mr. Chairman.

[Whereupon, at 5:22 p.m., the hearing was adjourned.]

[A submission for the record follows:]

Lilly

Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285

J. B. King
Vice President and General Counsel
(317) 276-2703

September 21, 1990

The Honorable Sam M. Gibbons
Chairman
Subcommittee on Trade
House Ways and Means Committee
United States House of Representatives
1136 Longworth House Office Building
Washington, D.C. 20515

Re: Duty Suspension on Ranitidine Hydrochloride

Dear Mr. Chairman:

I am writing on behalf of Eli Lilly and Company in support of H.R. 3130 and its companion bill, S. 1342. These bills would suspend temporarily the duty on ranitidine hydrochloride.

Eli Lilly and Company supports free trade and favors the elimination of duties on pharmaceutical products in the United States and worldwide.

Ranitidine hydrochloride is used in the production of Zantac®, an H2-antagonist that competes with Axid®, an H2-antagonist manufactured by Eli Lilly and Company for the treatment of ulcer disease.

We believe that temporary suspension of the duty on ranitidine hydrochloride would not negatively affect domestic competition and urge suspension of the duty.

Very truly yours,

JBK:cr